RX.PA.081.MPC Leqembi (lecanemab-irmb) IV and Subcutaneous

The purpose of this policy is to define the prior authorization process for Leqembi™ (lecanemab-irmb)

Leqembi™ (lecanemab-irmb) is an amyloid beta directed antibody indicated for the treatment of Alzheimer's disease.

PROCEDURE

A. Initial Authorization Criteria (Requests for Leqembi IV):

1. Alzheimer's Disease. All requests must meet the following criteria:

- Must be age 50 years or older
- Must have a documented diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease dementia as evidenced by all of the following:
    - Member must have a Clinical Dementia Rating (CDR) global score of 0.5 or 1
    - Member must have a Mini-Mental State Exam (MMSE) of greater than or equal to 22
    - Positron Emission Tomography (PET) scan or CSF assessment confirming presence of amyloid pathology (within 1 year)
    - Brain MRI prior to treatment (within 1 year)
        a. MRI must show no localized superficial siderosis
        b. Does not have more than 4 brain microhemorrhages (≤ 10mm in diameter)
        c. Must not have any brain hemorrhages (> 10mm in diameter)
        d. No vasogenic edema
        e. No cerebral contusion
        f. No aneurysms
        g. No vascular malformations/infective lesions
- Other causes of dementia have been ruled out (e.g. vascular dementia, Parkinson's disease, dementia, etc.)
    - Note: Leqembi will not be approved for members with Alzheimer's disease AND other causes of dementia
- Must be prescribed by a neurologist or geriatrician
- Dose does not exceed FDA approved indication
- Member must not be taking any anticoagulants or antiplatelet agents, other than aspirin 81mg daily or less
- Must not be used in combination with other amyloid beta-directed antibody therapies
- Must have an assessment of CNS bleed risk with no history of stroke/TIA within the

last year

- Member must have tried and failed for at least 3 months at least one of the following medications:
    - Acetylcholinesterase inhibitor (e.g. donepezil)
    - Memantine
- Member must obtain an MRI prior to the 3rd, 5th, 7th and 14th infusions for the IV product
- Results must not show an increase in size or number of Amyloid Related Imaging Abnormalities (ARIA)If member is on another medication for Alzheimer's treatment (acetylcholinesterase inhibitor, memantine), they must be on a stable dose for a minimum of 12 weeks

B. Reauthorization Criteria:

1. Alzheimer's Disease

MPC Renewal:

- All prior authorization renewals are reviewed on a 6 month interval basis to determine the Medical Necessity for continuation of therapy.
- Documentation of a clinical response, as determined by the prescriber
- Must be prescribed by a neurologist or geriatrician
- Cognitive testing of CDR (0.5 or 1) and MMSE (≥ 22) must be within 2 months to show improvement or stabilization of disease
- Assessment of CNS bleed risk with no history of stroke/TIA within the last year
- Member is not takin any anticoagulants of antiplatelet agents (except aspirin 81mg or less)
- Must not be used in combination with other amyloid beta-directed antibody therapies
- Provider attestation that benefits outweighs the risk of continued use and member's diagnosis has not progressed to moderate cognitive impairment
- Periodic MRI results must not show an increase in size or number of Amyloid Related Imaging Abnormalities (ARIA)
- Prior to the second MPC renewal, member must obtain an additional MRI prior to the 14th dose
    - Note: The additional MRI prior to the 14th dose only applies to the second renewal. Must have documentation of a clinical response, as determined by the prescriber or show stabilization of disease
- Request for Leqembi (lecanemab-irmb) subcutaneous only:
    - Members may be switched to maintenance therapy with Leqembi Subcutaneous after 18 months of initial IV therapy [Documentation required of initial IV therapy for 18 months]
    - Coverage for the subcutaneous formulation is not preferred.
    - Prescriber must supply clinical documentation to support why the subcutaneous formulation is medically necessary over the preferred IV formulation.
    - Prescriber must provide documentation of contraindication to the preferred Leqembi (lecanemab-irmb) IV product.
    - Provider must attest to obtaining an MRI and monitoring as clinically appropriate for the subcutaneous product

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC) and have been receiving Leqembi medication samples, should be considered under criterion A (Initial Authorization Criteria).
- Provider has a documented clinical response of the member's condition which has improved based or stabilized upon the prescriber's assessment

C. Leqembi (lecanemab-irmb) will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months for Leqembi IV product only
Reauthorization	Up to 6 months

Codes:

Code	Description
J0174	Injection, lecanemab-irmb, 1 mg

References:

1. Leqembi [package insert]. Nutley, NJ: Eisai Inc.; January 2023.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual policy review	*02/2026*
Addition of criteria requirements for the Leqembi™ (lecanemab-irmb) *subcutaneous formulation*	*10/2025*
Annual Review	*02/2025*
Annual policy review. Update to reauthorization criteria for non-MPC renewals	*02/2024*
New Policy	*06/2023*