POLICY NUMBER: RX.PA.081.MPC
REVISION DATE: 06/2023

RX.PA.081.MPC Leqembi (lecanemab-irmb)

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:

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.)
- 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 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 5th, 7th and 14th doses
    - 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 ~~6~~ 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

Non-MPC Renewal:

- Members who have previously been taking Leqembi (lecanemab-irmb) and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
- Member has not been receiving medication samples for (lecanemab-irmb)
- 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
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
New Policy	*06/2023*