Montana Healthcare Programs
Physician-Administered Drug (PAD) Criteria

# Leqembi® (lecanemab-irmb)

## I. Medication Description

Leqembi® is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease.

Leqembi® is 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.

## II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

## III. Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 50 years of age or older.
- Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or has mild Alzheimer's dementia stage of disease as evidenced by all the following:
  - Clinical Dementia Rating (CDR)-Global Score of 0.5
  - Mini-Mental Status Exam (MMSE) score between 22 and 30 and a Memory Box score of 0.5
  - Objective evidence of cognitive impairment at screening as indicated by at least 1 standard deviation below age-adjusted mean in the Wechsler-Memory Scale-IV Logical Memory II.
- Have a positive amyloid Positron Emission Tomography (PET) scan confirming presence of amyloid beta pathology.
- Have not had a stroke or transient ischemic attack (TIA) within the past year.
- Is not currently taking any medication with platelet anti-aggregate or anti-coagulant properties (unless aspirin ≤ 325 mg daily).
- Have an adequate trial of at least 6 months with a Montana Healthcare Programs preferred Alzheimer's therapy (cholinesterase inhibitor) and the preferred drug was ineffective or caused intolerable side effects.
  - List of Montana Healthcare Programs preferred drugs can be found at 19 (mt.gov).

- If taking medications to treat symptoms related to Alzheimer's disease, dosages must be stable for at least 12 weeks prior to starting Leqembi®. Additional therapies may not be initiated during Leqembi® treatment.

- Have a recent brain magnetic resonance imaging (MRI) (within one year) prior to initiating treatment.
- Have follow-up MRIs prior to the 5th, 7th and 14th infusions to evaluate for the presence of asymptomatic amyloid related imaging abnormalities (ARIA).

Prescriber requirements:

- Must be a neurology specialist.
- Have ruled out any other medical or neurological conditions (other than Alzheimer's disease) that may be contributing to member's cognitive impairment, including any medications that can substantially contribute to cognitive impairment (see Beer's List).
- Agree to MRIs done prior to the 5th, 7th and 14th infusions to evaluate for the presence of asymptomatic amyloid related imaging abnormalities (ARIA). Leqembi® can cause amyloid-related imaging abnormalities-edema (ARIA-E) and -hemosiderin deposition (ARIA-H)
  - For patients with radiographic findings of ARIA, enhanced clinical vigilance is recommended.
  - Additional MRIs may be considered if clinically indicated.
  - Interruption of treatment may be indicated per labeling based on severity of results.
- Prescriber attests to the following:
  - The prescriber is aware of the boxed warning (black box) of amyloid-related imaging abnormalities.
  - The prescriber is aware of the boxed warning of increased risk to patients who are apolipoprotein E ε4 homozygotes and has discussed this with patients at risk.

Limitations: Dosed per package labeling.

**IV. Renewal Coverage Criteria**

Member must meet all the following criteria:

- Have documentation of positive clinical response to Leqembi® therapy, as demonstrated by an improvement or stabilization from baseline on the Clinical Dementia Rating (CDR) and Mini-Mental Status Exam (MMSE).

Prescriber requirements:

- Be a neurology specialist.
- Obtain follow-up MRI prior to the 5th, 7th and 14th infusions.
- Monitor appropriately for ARIA. If imaging shows ARIA, manage treatment per labeling.

## V. Quantity Limits

Maximum Daily Dose = 10mg/kg infused over one hour every 2 weeks

## VI. Coverage Duration

Initial approval: 6 months

Renewal approval duration: 6 months

Reference:
https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf?hash=77aa4a86-b786-457a-b894-01de37199024