Mass General Brigham
Health Plan

Alzheimer's Agents
Leqembi (lecanemab-irmb)
Leqembi IQLIK (lecanemab-irmb)
Effective 04/01/2026

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Notes	Leqembi/Leqembi IQLIK are also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Leqembi (lecanemab-irmb) 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. It initially received accelerated approval similar to Aduhelm, but subsequently received a traditional approval after a clinical benefit was established. Of note, while Leqembi appears to be a safer alternative than Aduhelm, there a black box warning for amyloid-related imaging abnormalities (ARIA), particularly those patients who are apolipoprotein E (ApoE) ε4 homozygotes.

Coverage Guideline
Authorization may be granted for new members to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs, when continuation of therapy criteria is met.
OR
Authorization may be granted for members when all the following criteria are met:

Leqembi
1. Diagnosis of ONE of the following:
    a. Mild cognitive impairment (MCI)
    b. Mild dementia associated with Alzheimer's Disease (AD)
2. Prescriber is a specialist in the treatment of dementia or Alzheimer's disease (e.g., neurologist, geriatric psychiatrist, geriatrician who specializes in treating dementia)
3. Test results indicating clinically significant AD neuropathology based on ONE of the following:
    a. Amyloid PET
    b. Cerebral Spinal Fluid (CSF) biomarkers
4. Member has had a brain magnetic resonance imaging (MRI) within the last 12 months
5. Appropriate dosing

6. Baseline cognitive function test (within the last three months) based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE) score ≥ 22
    b. Montreal Cognitive Assessment (MoCA) score ≥ 15
    c. Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1

Leqembi IQLIK

1. Diagnosis of ONE of the following:
    c. Mild cognitive impairment (MCI)
    d. Mild dementia associated with Alzheimer's Disease (AD)
2. Prescriber is a specialist in the treatment of dementia or Alzheimer's disease (e.g., neurologist, geriatric psychiatrist, geriatrician who specializes in treating dementia)
3. Member has been treated with Leqembi (lecanemab-irmb) IV for at least 18 months
4. Appropriate dosing
5. Attestation all MRI monitoring has been completed in accordance with the FDA approved label
6. Current cognitive function test (date within the last three months) based on ONE of the following):
    a. Mini Mental State Exam (MMSE)
    b. Montreal Cognitive Assessment (MoCA)
    c. Saint Louis University Mental Status Examination (SLUMS)

<u>Continuation of Therapy</u>

Leqembi

First reauthorization:

1. Appropriate dosing
2. Attestation that all MRI monitoring has been completed in accordance with the FDA approved label
3. Current cognitive function test (within the past three months) based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE)
    b. Montreal Cognitive Assessment (MoCA)
    c. Saint Louis University Mental Status Examination (SLUMS)

Subsequent reauthorization (after completion of 18 months of treatment):

1. Attestation that all MRI monitoring has been completed in accordance with the FDA approved label
2. Current cognitive function test (within the past three months) based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE)
    b. Montreal Cognitive Assessment (MoCA)
    c. Saint Louis University Mental Status Examination (SLUMS)
3. ONE of the following:
    a. Dosing frequency reduced to every four weeks
    b. Clinical rationale for continuing biweekly dosing

Leqembi IQLIK

1. Appropriate dosing
2. All MRI monitoring has been completed in accordance with the FDA approved label
3. Current cognitive function test (dated within the last three months) based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE)

b. Montreal Cognitive Assessment (MoCA)
c. Saint Louis University Mental Status Examination (SLUMS)

Limitations

1. Initial approvals will be granted for:
    a. Leqembi: 6 months
    b. Leqembi IQLIK: 12 months
2. Reauthorizations will be granted for 12 months

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Review History

03/16/2022 – Reviewed and Created for March P&T; Match MH criteria Effective 05/01/2022.
01/11/2023 - Reviewed and updated for Jan P&T. Matched MH UPPL criteria. Adlarity was added to pharmacy benefit with PA and QL. Updated approval durations. Effective 3/1/23.
09/13/2023 – Reviewed and updated for P&T. Added Leqembi to criteria. Aduhelm initial criteria: Clarified provider specialty, SLUMS added as another assessment options, changed timeline of MRI scan from 3 to 12 months, and preferred trial of Leqembi. Aduhelm reauth criteria further simplified to require current objective assessments and attestation that all MRI monitoring has been completed. Effective 10/2/23
05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Removed Aduhelm due to removal from the market. Adlarity is removed as it is available on the pharmacy benefit and criteria is available on MHDL. Leqembi remains due to dual benefit. Criteria was updated to remove requirement of medical records and info on PA is acceptable. Reauthorization criteria has been split based on first and subsequent requests. Effective 6/1/25
3/11/26 – Reviewed and updated for P&T. Added Leqembi IQLIK to policy. Effective 4/1/26