Mass General Brigham
Health Plan

Alzheimer's Agents – Anti-Amyloid Antibodies: Kisunla (donanemab-azbt) Leqembi (lecanemab-irmb) Effective 01/01/2025

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Kisunla (donanemab-azbt) and Leqembi (lecanemab-irmb) are amyloid beta-directed antibodies indicated for the treatment of Alzheimer's disease. Treatment with Kisunla or Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted all of the following criteria are met:

<u>Kisunla and Leqembi</u>

1. Member has ONE of the following:
    a. Mild cognitive impairment (MCI)
    b. Mild dementia associated with Alzheimer's disease (AD)
2. Prescriber is a neurologist or geriatrics specialist consult notes from a neurologist or geriatrics specialist are provided
3. Medical records documenting Apolipoprotein E ε4 genetic testing to evaluate risk of amyloid related imaging abnormalities (ARIA)
4. Medical records documenting confirmed evidence of clinically significant AD neuropathology based on ONE of the following:
    a. Amyloid positron emission tomography (PET)
    b. Cerebral spinal fluid (CSF) **biomarkers**
5. Member has had a brain magnetic resonance imaging (MRI) within the last 12 months
6. Medical records documenting baseline (within the last 3 months) cognitive function based on ONE of the following objective assessments:

a. Mini Mental State Exam (MMSE) score of ≥ 22
b. Montreal Cognitive Assessment (MoCA) score of ≥15
c. Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1

7. Member does not have any conditions that would impact treatment (see Appendix)

Continuation of Therapy

Requests for reauthorization may be granted when all of the following criteria are met:

1. Member has achieved or maintained a positive clinical response to therapy
2. **Leqembi:** Provider attestation that MRI monitoring has been completed before the fifth, seventh, and fourteenth infusions, again after one year of treatment (i.e., prior to the 26th infusion) and then periodically guided by patient symptoms and prior MRI findings in accordance with the FDA approved label
   Kisunla: Provider attestation that MRI monitoring has been completed before the second, third, fourth, and seventh infusions.
3. Medical charts showing clinical benefit or delay in disease progression as documented by ONE of the following (within the last 3 months):
   a. Mini Mental State Exam (MMSE) score of ≥ 22
   b. Montreal Cognitive Assessment (MoCA) score of ≥15
   c. Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1
4. Member does not have any conditions that would impact treatment (see Appendix)

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months.

Appendix

Conditions Impacting Leqembi Treatment:

1. Any medical or neurological condition, other than AD, that might be a contributing cause of the individual's cognitive impairment
2. History of transient ischemic attack (TIA), stroke, or seizures in the past year
3. Contraindications to brain MRI scanning (e.g., non-MRI compatible implants)
4. Evidence of other clinically significant lesions on brain MRI that indicate another cause of the individual's cognitive impairment
5. Uncontrolled bleeding disorder (including platelet count <50,000 or INR >1.5)
6. Use of anticoagulants and/or antiplatelet medications or concomitant use has been evaluated by physician
7. Any uncontrolled immunological disease or immunological disease requiring treatment with immunoglobulins, systemic monoclonal antibodies, systemic immunosuppressants, or plasmapheresis

Conditions Impacting Kisunla Treatment:

1. Significant neurological disease affecting the central nervous system other than AD
2. Serious conditions (e.g., cardiovascular, hepatic, renal, gastroenterological, respiratory, endocrinologic, neurologic [other than AD], psychiatric, immunologic, or hematologic disease) that can impact analysis of results or shorten lifespan of patients to less than 24 months
3. Presence of ARIA-E (amyloid-related imaging abnormalities-edema) or ARIA-H (amyloid-related imaging abnormalities-cerebral microhemorrhage)

References

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Review History

10/11/2023 - Reviewed at October P&T, Effective 12/1/23
10/09/2024 – Reviewed and updated at October P&T. Added Kisunla to the policy. Removed "appropriate dosing" from initial and reauthorization criteria. Updated reauthorization criteria to include MRI monitoring parameters for Kisunla. Updated Appendix to include conditions that would impact Kisunla treatment. Effective 1/1/2025.