Mass General Brigham
Health Plan

Alzheimer's Agents
Kisunla (donanemab-azbt)
Effective 02/28/2025

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		
Notes	Kisunla is 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
Kisunla (donanemab-azbt) is an amyloid beta-directed antibodies indicated for the treatment of Alzheimer's disease. Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease.

Coverage Guidelines
Authorization may be reviewed on a case-by-case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

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. Medical records documenting confirmed evidence of 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. Medical records documenting baseline (within the last three months) cognitive function based on **ONE** of the following objective assessments:

a. Mini Mental State Exam (MMSE) score ≥ 20
b. Montreal Cognitive Assessment (MoCA) score ≥ 15
c. Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1

Continuation of Therapy

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

Limitations

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

References

1. Kisunla [package insert]. Indianapolis (IN): Eli Lilly and Company; 2024 July.

Review History

12/11/24 – Created criteria for P&T. Kisunla will be managed as dual benefit, therefore medical criteria was created to be posted on MGBHP website (note: no preferred product requirement). Rx will be available on MHDL. Effective 2/28/2025