

**Alzheimer's Agents**  
**Kisunla (donanemab-azbt)**  
**Effective 09/01/2025**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Contact Information</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Notes</b>	Kisunla is also available on the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> for coverage and criteria.  Additional agents from this class are available through the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> 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. 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 (dated within the last three months) based on **ONE** of the following objective assessments:
  - a. Mini Mental State Exam (MMSE) score  $\geq 20$

- b. Montreal Cognitive Assessment (MoCA) score  $\geq 15$
- c. Saint Louis University Mental Status Examination (SLUMS) score  $\geq 16.1$

#### **Continuation of Therapy**

- 1. Appropriate dosing
- 2. Attestation that all MRI monitoring has been completed in accordance with the FDA approved label
- 3. Current cognitive function test (dated 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. 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

8/13/25 – Reviewed and updated for P&T. Verbiage update on function tests and baseline tests by not stating “medical records”. This aligns with the posted criteria on MHDL. Effective 9/1/25.

