

# MEDICAL REVIEW GUIDELINE

Kisunla Diagnosis Specific Policy



## Kisunla™ (Donanemab-azbt)

Effective Date: 11/1/2025

Medical Care Management Committee Approval: 7/17/25

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### Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Kisunla™ (Donanemab-azbt) product:

HCPCS Code	Description	Maximum Dosage per Administration
J0175	Injection, donanemab-azbt, 2 mg	1400 mg

### Diagnosis-Specific Criteria

Kisunla™ (Donanemab-azbt) will be considered medically necessary and authorized for 6 months for members meeting ALL of the following criteria:

1. Age 60-85 years
2. Prescribed by or in consultation with a neurologist
3. Documentation of gradual and progressive change in memory function for at least 6 months
4. Diagnosis of mild cognitive impairment from Alzheimer's disease (AD) or mild AD dementia confirmed by ALL of the following within previous 6 months, documentation required:
  - a. Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0
  - b. CDR Memory Box Score of at least 0.5
  - c. Mini-Mental Status Exam (MMSE) score between 20-30
5. Presence of amyloid beta pathology confirmed by positron emission tomography (PET) scan or cerebrospinal fluid (CSF) lumbar puncture, documentation required.
6. Member will not be treated concurrently with any of the following: anticoagulant, immunoglobulins, systemic monoclonal antibodies or immunosuppressants

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7. Member will not be treated concurrently with another amyloid targeting therapy (Leqembi, etc)
8. Member does not have a history of transient ischemic attack (TIA), stroke, seizure or bleeding disorder within previous 12 months

### Continuation Criteria

1. Member has been previously approved by Community Health Choice or another health plan with submitted evidence of a paid claim within 3 months prior to authorization request, or member meets all of the initial request criteria above.
2. Prescribed by or in consultation with a neurologist
3. Member continues to have mild cognitive impairment with ALL of the following measured no more than 1 month prior to authorization renewal request:
  - a. Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0
  - b. CDR Memory Box Score of at least 0.5
  - c. Mini-Mental Status Exam (MMSE) score between 20-30
4. Member has not experienced any adverse effects such as amyloid related imaging abnormalities edema (ARIA-E) and -hemosiderin deposition (ARIA-H), intracerebral hemorrhage, or severe hypersensitivity reactions necessitating discontinuation of therapy
5. Documentation showing amyloid plaque levels have NOT reached ONE of the following criteria for discontinuation of donanemab-azbt (Kisunla) therapy:
  - a. Level is less than 11 Centiloids on a single PET scan
  - b. Level is 11 to less than 25 Centiloids on two consecutive PET scans
6. Member will not be treated concurrently with another amyloid targeting therapy (Leqembi, etc)

### Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPSC Code	Description
J0175	Injection, donanemab-azbt, 2 mg

Diagnosis Code	Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified

### Policy Revision History

Status	Effective Date	Description
Baseline	10/1/25	Initial version of donanemab-azbt diagnosis specific policy