Evolent Clinical Guideline 5108.CC for Kisunla (Donanemab)

Guideline Number:	Applicable Codes	
Evolent_CG_5108.CC		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. 		
Original Date:	**Last Revised Date:**	**Implementation Date:**
December 2025	October 2025	December 2025

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline to define the prior authorization process for Kisunla (donanemab).

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a neurologist or gerontologist
- Must have a diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia, as defined by **both** of the following:
  - Confirmation of diagnosis using ONE of the following cognitive/functional clinical outcome assessment tools:
    - Clinical Dementia Rating-Global Score (CDR-GS) score of 0.5
    - Mini-Mental State Examination (MMSE) score between 20 and 28
    - Montreal Cognitive Assessment (MoCA) score ≥17
  - Must have positron emission tomography (PET) or cerebrospinal fluid (CSF) test confirming amyloid beta pathology
- Must have a baseline brain magnetic resonance imaging (MRI) prior to initiating therapy
- Must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must have chart note documentation or an attestation from the provider of all the following:
  - All other causes of dementia (e.g., HIV dementia, dementia of Huntington's disease) have been ruled out
  - The member is not on concomitant therapy with antithrombotics or antiplatelets

(excluding aspirin 81 mg)

- The member has not had a brain hemorrhage, bleeding disorder, cerebrovascular abnormality, or significant conduction abnormality in the last 12 months, including:
  - Stroke
  - Transient ischemic attack (TIA)
  - Unstable angina
  - Myocardial infarction
  - Advanced chronic heart failure

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed below:

- The member's condition has improved based upon the prescriber's assessment while on therapy, demonstrated by improvement OR stabilization in baseline cognitive scoring (e.g., CDR-GS, MMSE, MoCA)
- Must have chart note documentation or an attestation from the provider of all the following:
  - The member has no evidence of intolerable adverse effects or drug toxicity such as Amyloid Related Imaging Abnormalities (ARIA)
  - MRIs are being completed prior to the 2nd, 3rd, 4th, and 7th infusions, and as clinically indicated
  - If the member has symptoms suggestive of ARIA, the member has been evaluated and a medical necessity statement is provided supporting on-going treatment
- Must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

APPROVAL DURATIONS

Initial Authorization	Up to 1 year
Reauthorization	Same as initial

CODING AND STANDARDS

Codes

Code	Brand	Description
J0175	Kisunla	Injection, donanemab-azbt, 2mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

KISUNLA is an amyloid beta-directed antibody 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, the population in which treatment was initiated in the clinical trials.

POLICY HISTORY

Date	Summary
October 2025	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent

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REFERENCES

1. Kisunla [package insert]. Indianapolis (IN): Eli Lilly and Company; 2024 Jul.
2. Alzheimer's Association. Clinical practice guideline for the diagnostic evaluation of Alzheimer's disease and related disorders (DETeCD-ADRD). Alzheimers Dement. 2023;19(1):Article 14335. Available from: https://doi.org/10.1002/alz.14335
3. Wilterdink JL, DeKosky ST. Amyloid-targeted therapies for the treatment of Alzheimer disease. In: UpToDate. UpToDate, Inc.; 2024 [cited 2025 Feb 4]. Available from: https://www.uptodate.com/contents/amyloid-targeted-therapies-for-the-treatment-of-alzheimer-disease?search=kisunla&source=search_result&selectedTitle=2~5&usage_type=default&display_rank=1#H2476789382