Reference number(s)
6559-A

Standard Medicare Part B Management Kisunla

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kisunla	donanemab-azbt

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Kisunla is 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.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

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Initial Requests

- Medical records (e.g., chart notes) documenting the following:
  - Diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild AD dementia.
- Presence of amyloid pathology consistent with AD.
- Physician participation in a CMS-approved Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry via CMS-facilitated portal with an appropriate clinical team and follow-up care.

Continuation Requests

Continued physician participation in a CMS-approved Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry via CMS-facilitated portal with an appropriate clinical team and follow-up care.

Exclusions

Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) provided outside of an FDA approved randomized controlled trial, CMS-approved studies, or studies supported by the National Institutes of Health (NIH), are nationally non-covered.

Coverage Criteria

Alzheimer's Disease[1-4]

Authorization of 7 months may be granted for treatment of Alzheimer's disease (AD) when all of the following criteria are met:

- Member must have mild cognitive impairment (MCI) due to AD or mild AD dementia.
- Member has confirmed presence of amyloid beta pathology consistent with AD.
- The requested drug is furnished according to the FDA approved indication in National Institutes of Health (NIH)-supported trials.
- Member has a physician participating in a CMS-approved Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry via CMS-facilitated portal with an appropriate clinical team and follow-up care.

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Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Kisunla.
- Kisunla is being used to treat an indication listed in the coverage criteria section.
- Member has a physician that continues to participate in a CMS-approved Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry via CMS-facilitated portal with an appropriate clinical team and follow-up care.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Kisunla.
- National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Kisunla are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Using Kisunla to treat mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease (AD) dementia is covered according to the conditions outlined in National Coverage Determination Manual section 200.3 - Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease.

References

1. Kisunla [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2025.
2. National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (200.3 – Version 1). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1 Accessed January 12, 2026.
3. Centers for Medicare and Medicaid Services. Fact Sheet. June 22, 2023. Accessed January 12, 2026. https://www.cms.gov/files/document/fact-sheet-june-2023.pdf.

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4. Centers for Medicare and Medicaid Services. HPMS Memos. November 25, 2025. Accessed January 12.2026. https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-november-24-28.

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