Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
# Kisunla (donanemab-azbt)

*Effective: March 1, 2026*

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|---|---|
| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

**Senior Products**

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration (FDA) - Approved Indications:**

**Kisunla (donanemab-azbt)** 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.

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of Kisunla (donanemab-azbt) for Members when **ALL** of the following criteria are met:

***Initial criteria***

1. Documented diagnosis of one of the following:
   a. Mild cognitive impairment due to Alzheimer's disease
   b. Mild dementia due to Alzheimer's disease

**AND**

2. Member is between 60 to 85 years of age

**AND**

3. Prescribed by a Neurologist, Geriatric Psychiatrist, or Neuropsychiatrist who specializes in the treatment of Alzheimer's Disease

**AND**

4. Documentation of both of the following:
   a. Member had a mini-mental state examination (MMSE) score of 20–28 at baseline
   b. Member had a progressive change in memory function for at least 6 months

**AND**

5. Documentation confirming the presence of amyloid beta pathology as evidenced by one of the following:
   a. Positive amyloid positron emission tomography (PET) scan
   b. Cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., Aβ42 level, Aβ42:Aβ40 ratio, Tau, p-Tau)

**AND**

6. Documentation that the member's symptoms are not related to another neurological or psychiatric condition

**AND**

7. Documentation that the member has had a baseline brain magnetic resonance imaging (MRI) completed within 12 months prior to initiating treatment with Kisunla

**AND**

8. Documentation that the member has had genotype testing for apolipoprotein E ε4 (ApoE ε4) status performed prior to initiation of treatment to evaluate risk of amyloid related imaging abnormalities (ARIA)

**AND**

9. If member is homozygous for the ApoE ε4 gene, documentation that the member has been counseled that they are at increased risk for ARIA and the member and provider has determined that the benefits outweigh the risks

**AND**

10. Documentation that the prescriber will monitor for amyloid-related imaging abnormalities (ARIA) via MRI prior to initiation and prior to the 2nd, 3rd, 4th, and 7th infusions of Kisunla

**AND**

11. Documentation that the member has no history of cerebrovascular abnormalities or bleeding disorder that would present a risk for ARIA-related bleeding

**AND**

12. Documentation that the member has no history of brain hemorrhage, bleeding disorders, cerebrovascular abnormalities, stroke or Transient Ischemic attack (TIA)

***Reauthorization criteria***

1. One of the following:
    a. If requesting for the first reauthorization, medical records confirming that follow up MRI monitoring have been completed prior to the 2nd, 3rd, 4th infusion of Kisunla
    b. If requesting for the second reauthorization, medical records confirming that follow up MRI monitoring have been completed prior to the 7th infusions of Kisunla

**AND**

2. Documentation that the member continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease or mild dementia due to Alzheimer's disease

## Limitations

- Initial authorization of Kisunla is limited to 6 months.
- Reauthorization of Kisunla is limited to 6 months. Maximum of two reauthorizations will be granted.
- Coverage of Kisunla treatment beyond 76-week will not be authorized as there is no data to support additional dosing with Kisunla past 76 weeks provides longer-term clinical benefit.
- Members new to the plan and stable on Kisunla should be reviewed against reauthorization criteria.

## Codes

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

| HCPCS Codes | Description |
|---|---|
| J0175 | Injection, donanemab-azbt, 2mg |

## References


1. Kisunla (donanemab) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; July 2025.
2. Sims, John R., et al. "Donanemab in early symptomatic Alzheimer disease: the TRAILBLAZER-ALZ 2 randomized clinical trial." *Jama* 330.6 (2023): 512-527.
3. Mintun, Mark A., et al. "Donanemab in early Alzheimer's disease." New England Journal of Medicine 384.18 (2021): 1691-1704.
4. Porsteinsson, Anton P., et al. "Diagnosis of early Alzheimer's disease: clinical practice in 2021." *The journal of prevention of Alzheimer's disease* 8 (2021): 371-386.
5. Jack Jr, Clifford R., et al. "Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup." Alzheimer's & Dementia (2024).

## Approval And Revision History

September 10, 2024: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- January 14, 2025: Effective April 1, 2025, added criterion for apolipoprotein E ε4 (ApoE ε4) status prior to initiation of treatment.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- February 10, 2026: no changes. Administrative update: removed Carelink from template.

## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.