Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Kisunla™ (donanemab)

Effective: July 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Public Plans Products

☒ 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

On July 2, 2024, the U.S. FDA approved branded Kisunla injection for the treatment of AD. FDA approval was based on the safety and efficacy data from a double-blind, placebo-controlled, parallel-group, multicenter study (TRAILBLAZER-ALZ 2; NCT04437511) in adult patients with AD. All patients had confirmed presence of amyloid pathology and mild cognitive impairment or mild dementia stage of disease.

CMS announced its final Medicare national coverage determination (NCD) that covers FDA approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) when furnished in accordance to the Coverage Criteria specified under coverage with evidence development (CED) for patients who have a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD.

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.

Monoclonal antibodies directed against aggregated forms of beta amyloid, including KISUNLA, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with KISUNLA.

Patients who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including KISUNLA, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with KISUNLA; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Kisunla for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria:

1. Documentation is submitted that confirms diagnosed of mild cognitive impairment or early dementia caused by Alzheimer's disease

AND

2. Kisunla must be prescribed by a qualified physician participating in a CMS-approved Monoclonal Antibodies Against Amyloid for the Treatment of Alzheimer's Disease CED Study registry, with an appropriate clinical team and follow up

care

Note- *registries are common tools in clinical settings that have successfully gathered information on patient outcomes for decades. There is strong precedent for using registries to gather more information on a newly approved treatment*

AND

3. Member has confirmation of the presence of amyloid beta pathology prior to initiating treatment

Reauthorization Criteria:

The Plan may authorize coverage of Kisunla for Members when all of the following criteria are met:

1. The member continues to participate in a CMS-approved Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry with an appropriate clinical team and follow-up care
2. Documentation the member has had follow up MRI's

Limitations

- Kisunla will not be covered for an earlier or later stages of Alzheimer's Disease
- Initial authorization of Kisunla is limited to a total of 6 months if initial authorization criteria are met
- Reauthorization for Kisunla may be granted for a period of up to 6 months when reauthorization criteria are met
- 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.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0175	Injection, donanemab-hyphenazbt, 2 mg

References:

1. Eli Lilly and Company. Kisunla (donanemab-azbt) injection, for intravenous use. Prescribing Information. Indianapolis, IN: Eli Lilly; revised July 2024
2. National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (200.3 – Version 1).

Approval And Revision History

December 2024: Reviewed by Pharmacy and Therapeutics Committee (P&T) effective Jan 1, 2025

December 2024: Joint Medical Policy and Health Care Services UM Committee review effective Jan 1, 2025

Subsequent endorsement date(s) and changes made:

- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)
- June 2026: Joint Medical Policy and Health Care Services UM Committee review; removed required attestation that the provider has discussed performing genotype testing for apolipoprotein E ε4 (ApoE ε4) status prior to initiation of treatment (effective 7/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.