

Kisunla™ (donanemab-azbt)

When requesting Kisunla™ (donanemab-azbt), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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 clinical trials.

Coverage Guidelines

Alzheimer's Disease

The individual must meet the following criteria for an initial authorization:

1. Has mild cognitive impairment due to Alzheimer's disease or mild dementia due to Alzheimer's disease;
2. Has had one of the following baseline assessments:
 - a. Clinical Dementia Rating-Global Score (CDR-GS); OR
 - b. Mini-Mental State Examination (MMSE); OR
 - c. Montreal Cognitive Assessment (MoCA); OR
 - d. Saint Louis University Mental Status (SLUMS); OR
 - e. Rowland Universal Dementia Assessment Scale (RUDAS);
3. Meets ALL of the following:
 - a. Has had a magnetic resonance imaging (MRI) of the brain within the past 1 year; AND
 - b. The MRI showed ≤ 4 brain microhemorrhage, brain hemorrhage ≤ 1 cm, and ≤ 1 pre-treatment localized superficial siderosis; AND
 - c. Ruled out medical or neurological conditions, other than Alzheimer's disease, that may be contributing to the patient's cognitive impairment;
4. Has had a positive test for amyloid beta based on Positron Emission Tomography (PET) scan OR cerebrospinal fluid (CSF) beta-amyloid;
5. Kisunla is prescribed by or under the supervision of a neurologist.

The individual must meet the following criteria for re-authorization:

1. Has not progressed beyond mild dementia due to Alzheimer's disease;
2. Has undergone MRI monitoring for amyloid related imaging abnormalities (ARIA) and meets one of the following:
 - a. Does not have ARIA; OR
 - b. Continuation of therapy is appropriate;
3. Kisunla is prescribed by or under the supervision of a neurologist.

Approval Duration (initial): 6 months
Approval Duration (renewal): 12 months

Dosing Recommendation

Kisunla is administered as an intravenous infusion over approximately 30 minutes every four weeks as follows:

Intravenous Infusion (every 4 weeks)	Kisunla Dosage
Infusion 1	350 mg
Infusion 2	700 mg
Infusion 3	1,050 mg
Infusion 4 and beyond	1,400 mg

References

1. Kisunla™ intravenous infusion [prescribing information]. Indianapolis, IN: Lilly; July 2025.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2025. Available at: <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>. Accessed on February 18, 2026.
3. Sims JR, Zimmer JA, Evans CD, et al, for the TRAILBLAZER-ALZ 2 Investigators. Donanemab in early symptomatic Alzheimer disease: The TRAILBLAZER-ALZ 2 randomized clinical trial. *JAMA*. 2023;330(6):512-527.
4. Zimmer JA, Sims JR, Evans CD, et al. Donanemab in early symptomatic Alzheimer's disease: results from the TRAILBLAZER-ALZ 2 long-term extension. *J Prev Alzheimer's Dis*. Published online December 1, 2025.