Corporate Medical Policy: Donanemab-azbt (Kisunla™)

Restricted Product(s):

- donanemab-azbt (Kisunla™) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- For the treatment of Alzheimer's disease. Treatment 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.*

*Use of donanemab-azbt (Kisunla™) is considered investigational for this indication due to insufficient clinical evidence to establish safety, efficacy, and improved health outcomes.

Criteria for Medical Necessity:

Not applicable

The use of donanemab-azbt (Kisunla™) is considered investigational for all indications including treatment of Alzheimer's disease. BCBSNC does not provide coverage for investigational services or procedures.

- The use of donanemab-azbt (Kisunla™) is considered investigational for all indications including treatment of Alzheimer's disease

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units**
donanemab-azbt (Kisunla™) intravenous (IV) infusion	Alzheimer's disease	IV every 4 weeks • Infusion 1: 350 mg • Infusion 2: 700 mg • Infusion 3: 1,050 mg • Infusion 4 and beyond: 1,400 mg Consider stopping treatment based on reduction of amyloid plaques to minimal levels on amyloid PET imaging.	J0175	**N/A**

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Institute for Clinical and Economic Review. Beta-amyloid antibodies for early Alzheimer's disease. Draft Evidence Report. December 22, 2022 [Updated January 4, 2023]. https://icer.org/wp-content/uploads/2021/12/ICER_Alzheimers-Disease_Draft-Report_12222022-1.pdf. Accessed September 2024.
2. Sims JR, Zimmer JA, Evans CD, et al. Donanemab in early symptomatic Alzheimer disease: the TRAILBLAZER-ALZ 2 randomized clinical trial. *JAMA*. 2023;330(6):512-527.
3. Sperling RA, Jack CR Jr, Black SE, et al. Amyloid-related imaging abnormalities in amyloid-modifying therapeutic trials: recommendations from the Alzheimer's Association Research Roundtable Workgroup. *Alzheimers Dement*. 2011;7(4):367-385.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

November 2025: Criteria update: Updated FDA label reference table and dosing according to FDA label.
September 2024: Original medical policy criteria issued: Use of donanemab-azbt is considered investigational for all indications including treatment of Alzheimer's disease.