donanemab-azbt (Kisunla)

Commercial Medical Benefit Drug Policy

Place of Service

Infusion Center Administration
Home Infusion Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Amyloid beta-directed antibody
HCPCS:
J0175:Injection, donanemab-azbt, 2 mg
How Supplied:
350 mg/20 mL (17.5 mg/mL) in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Alzheimer's Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Alzheimer's Disease

Meets medical necessity if all the following are met:

1. Being prescribed by or in consultation with a neurologist, geriatrician, or geriatric psychiatrist
2. Meets ONE of the following:
   a. Positive for beta amyloid pathology based on PET scan
   b. Lumbar puncture results confirming the presence of elevated P-tau, and/or T-tau protein and reduced beta amyloid-42, or a low AB42/AB40 ratio as determined by lab assay detected in cerebral spinal fluid

3. Diagnosis of mild cognitive impairment (MCI) or mild dementia due to AD as determined by one of the following:
   a. Clinical Dementia Rating Global Score (CDR-GS) of 0.5 to 1
   b. Montreal Cognitive Assessment (MoCA) score ≥16
   c. Mini Mental State Exam (MMSE) score of 20-28
4. Patient does not have a history of transient ischemic attack, stroke, or seizures within the past 12 months
5. No significant pathological findings on pre-treatment magnetic resonance imaging (MRI) scan within the last 12 months to rule out pre-existing amyloid related imaging abnormalities (ARIA) or other irregular findings (e.g., cerebral contusions, encephalomalacia, aneurysms, vascular malformations, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, etc.) that may increase the likelihood of significant adverse events
6. Patient is not currently receiving anticoagulant therapy except for aspirin at a prophylactic dose or less (i.e., ≤ 325mg)

Covered Doses:
Up to 350 mg given intravenously for the first dose, 700 mg given for the second dose, 1,050 mg given for the third dose, followed by 1,400 mg given every 4 weeks thereafter

Coverage Period:
Initial authorization: 6 months
Reauthorization: 12 months if meets the below criteria:
1. Prescribed by or in consultation with a neurologist, geriatrician, or geriatric psychiatrist
2. Patient has not progressed beyond MCI or mild dementia related to AD as determined by ONE of the following:
   a. CDR-GS >1
   b. MoCA <16
   c. MMSE <20
3. Amyloid PET imaging results that support the continued use of Kisunla as indicated by one of the following:
   a. Amyloid plaque level is ≥11 centiloids on a single PET scan
   b. Amyloid plaque level is ≥25 centiloids on two consecutive PET scans
4. Patient does not have any of the following based upon the results of monitoring MRI scans:
   a. Moderate-to-severe ARIA-E symptoms or any ARIA-H symptoms
   b. Asymptomatic but moderate to severe radiographic findings of ARIA-E and/or ARIA-H
   c. Presence of intracerebral hemorrhage greater than 1 cm in diameter

ICD-10:
G30.9

References

1. Kisunla (donanemab-azbt) Prescribing Information. Eli Lilly and Company, Indianapolis, IN. 7/2024.

Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- Updated covered doses to align with new FDA dosing

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee