ALASKA MEDICAID
Prior Authorization Criteria

Kisunla
(donanemab-azbt)

FDA INDICATIONS AND USAGE[1]

Kisunla 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 clinical trials.

APPROVAL CRITERIA[1,2,3]

1. Patient is 50 years of age or older **AND**;
2. Prescribed by or in consultation with a neurologist **AND**;
3. Patient has the diagnosis of Alzheimer's disease **AND**;
4. Patient has the presence of beta-amyloid plaques verified by either a positron emission tomography (PET) scan or cerebrospinal fluid (CSF) testing **AND**;
5. Patient must have a documented brain magnetic resonance imaging (MRI) within the last year showing no localized superficial siderosis, has less than 4 brain microhemorrhages, and no brain hemorrhages that are greater than 1 cm in the past year **AND**;
6. Must have objective evidence of cognitive impairment at screening **AND**;
7. Patient has a Clinical Dementia Rating (CDR) global score of 0.5 or 1 **AND**;
8. Patient has a Mini-Mental State Exam (MMSE) between 20 and 28 **AND**;
9. Other known causes of dementia have been ruled out (e.g. vascular dementia, Parkinson's disease dementia, etc.)

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient will be taking concurrently with other anti-amyloid immunotherapies **OR**;
3. Patient has had a brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities in the last 6 months **OR**;
4. Patient has a significant systematic illness or infection in past 30 days **OR**;
5. Patient amyloid plaque level has decreased to <11 Centiloids on a single PET scan or <25 Centiloids on two consecutive PET scans.
6. Patient has a history of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within 1 year prior to Screening

CAUTIONS[1]

- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated.
- Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E ε4 (ApoE ε4) homozygotes compared to heterozygotes and noncarriers.

- The most common adverse reactions include infusion reactions, ARIA-Edema, headache, ARIA-H microhemorrhage, and ARIA-H superficial siderosis.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if:
- ARIA mitigation protocol has been followed per FDA guidance **AND;**
- Documented evidence the patient is responding positively, has slowed the rate of cognitive decline, and evidence of no adverse reactions.

QUANTITY LIMIT

- Per FDA label approved protocol
  - Maximum 1400mg (#4 350mg/20ml) vials infused intravenously every 28 days
- HCPCS: J0175

REFERENCES / FOOTNOTES:

1. Kisunla (donanemab-azbt) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; July 2024
2. Sims J, Zimmer J, Evans C, et al.; Donanemab in early symptomatic Alzheimer disease: the TRAILBLAZER-ALZ 2 randomized clinical trial. JAMA. 2023;330(6):512-527. DOI: 10.1001/jama.2023.13239.
3. Institute for Clinical and Economic Review: Draft Evidence Report – Beta-Amyloid Antibodies for Early Alzheimer's Disease. December 22, 2022. Available at: https://icer.org/wp-content/uploads/2021/12/ICER_Alzheimers-Disease_Draft-Report_12222022-1.pdf.