Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 18, 2025

Kisunla™ (donanemab-azbt)

LENGTH OF AUTHORIZATION: Six months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient has mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or has mild Alzheimer's dementia (there is insufficient evidence in moderate or severe AD) as evidenced by **ALL** the following:
  - Clinical Dementia Rating (CDR)-Global Score of 0.5 to 1
  - Memory Box Score of ≥ 0.5
  - Objective evidence of cognitive impairment at screening
  - Mini-Mental State Examination (MMSE) score between 20 to 28, inclusive
  - Positron Emission Tomography (PET) scan or cerebrospinal fluid (CSF) assessment of amyloid ß (Aß 1-42) is positive for amyloid beta plaque; **AND**
- Other conditions mimicking, but of non-Alzheimer's dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]); **AND**
  - Patient has been tested prior to treatment to assess apolipoprotein E ε4 (ApoE ε4) status (e.g., homozygote, heterozygote, or noncarrier), and the prescriber has informed the patient that those who are homozygotes have a higher incidence of developing amyloid related imaging abnormalities (ARIA); **OR**
  - Genotype testing has not been performed, and the prescriber has informed the patient that it cannot be determined if they are ApoE ε4 homozygotes and, therefore, it also cannot be determined whether they are at higher risk for developing ARIA; **AND**
- Patient has received a baseline brain magnetic resonance imaging (MRI) prior to initiating; **AND**
- Patient does NOT have a clinically significant and unstable psychiatric illness in the past 6 months; **AND**
- Patient does NOT have a history of alcohol or substance abuse in the preceding year; **AND**
- Medication will NOT be used concurrently with other anti-amyloid immunotherapies (e.g., lecanemab [Leqembi®], aducanumab [Aduhelm®]); **AND**
- Must be prescribed by, or in consultation with, a specialist in neurology or gerontology.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**

- Patient has responded to therapy compared to pretreatment baseline as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in ≥ 1 of the following (not all-inclusive): ADAS-Cog 13; ADCS-ADL-MCI; MMSE; CDR-SB; **AND**
- Patient will discontinue treatment when reduction of amyloid plaques are reduced to minimal levels on amyloid PET imaging, defined as either of the following:
    - Level is < 11 Centiloids on a single PET scan; **OR**
    - Level is 11 to < 25 Centiloids on 2 consecutive PET scans; **AND**
- Patient has NOT progressed to moderate or severe AD; **AND**
- Patient has undergone MRI prior to the 2nd, 3rd, 4th, AND 7th infusion to monitor ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H) microhemorrhages; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include ARIA-E and ARIA-H, intracerebral hemorrhage, and severe infusion-related reactions including anaphylaxis; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 350 mg/20 mL (17.5 mg/mL) in single-dose vial.