CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Kisunla (donanemab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Kisunla, approved by the FDA in 2024, 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 (stage 3 or 4), the population in which treatment was initiated in clinical trials. Alzheimer's disease is a neurodegenerative disease associated with cognitive, functional, and behavioral impairments. It is thought to be caused by the increasing accumulation of amyloid beta (Aβ) plaques and neurofibrillary tangles (NFTs) formed by aggregated tau protein. Kisunla targets deposited amyloid plaque and has been shown to lead to plaque clearance in treated patients.
Kisunla has a black box warning for amyloid related imaging abnormalities (ARIA). ApoE ε4 homozygotes have a higher incidence of ARIA.

Kisunla (donanemab) will be considered for coverage when the following criteria are met:

Alzheimer's Disease

For **initial** authorization:

1. Member is at least 60 of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or geriatrician; AND
3. Member has a diagnosis of early Alzheimer's disease with mild cognitive impairment due to Alzheimer's disease OR mild Alzheimer's disease–related dementia; AND
4. Presence of amyloid beta pathology has been confirmed by **ONE** of the following:
   a) Positron-emission tomography (PET) scan imaging;
   b) Cerebrospinal fluid (CSF) lumbar puncture; AND
5. Member has had a progressive change in memory function for at least 6 months; AND
6. Documentation of Mini Mental State Examination (MMSE) score of 20 to 28; AND
7. Member has had a brain MRI in the past 12 months to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA); AND
8. Member's ApoE ε4 status has been or will be determined before starting treatment (must provide documentation of results or pending order for testing); AND
9. If member is on an anticoagulant, provider attests that safety risks for ARIA have been discussed and member is on a stable dose; AND
10. Member does **NOT** have ANY of the following:
    a) Transient ischemic attacks (TIA), stroke, or seizures within the last 12 months;
    b) Contraindication to MRI;
    c) Inadequately controlled bleeding disorder.
11. **Dosage allowed/Quantity limit:** administer 700 mg intravenously every four weeks for three doses, then 1400 mg intravenously every four weeks. Quantity limit: 4 vials per 28 days after induction dosing.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member has had a follow up assessment including cognitive test(s) to determine that they have not progressed to moderate/severe dementia; AND
2. Documentation of continued MRI monitoring for amyloid related imaging abnormalities with edema (ARIA-E) and with hemosiderin deposition (ARIA-H), as per prescribing information.

If all the above requirements are met, the medication will be approved for an additional 6 months.

CareSource considers Kisunla (donanemab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/23/2024	New policy for Kisunla created.

References:

1. Kisunla [prescribing information]. Eli Lilly and Company; 2024.
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3. McKhann GM, Knopman DS, Chertkow H, et al. The diagnosis of dementia due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. *Alzheimers Dement.* 2011;7(3):263-269. doi:10.1016/j.jalz.2011.03.005
4. Porsteinsson AP, Isaacson RS, Knox S, Sabbagh MN, Rubino I. Diagnosis of Early Alzheimer's Disease: Clinical Practice in 2021. *J Prev Alzheimers Dis.* 2021;8(3):371-386. doi:10.14283/jpad.2021.23
5. Centers for Medicare & Medicaid Services (CMS): Medicare Coverage Database. Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD). National Coverage Determination (NCD). 04/07/2022. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1
6. Jack CR Jr, Andrews JS, Beach TG, et al. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. *Alzheimers Dement.* Published online June 27, 2024. doi:10.1002/alz.13859
7. Jack CR Jr, Bennett DA, Blennow K, et al. NIA-AA Research Framework: Toward a biological definition of Alzheimer's disease. *Alzheimers Dement.* 2018;14(4):535-562. doi:10.1016/j.jalz.2018.02.018
8. 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. doi:10.1001/jama.2023.13239
9. Ramanan VK, Armstrong MJ, Choudhury P, et al. Antiamyloid Monoclonal Antibody Therapy for Alzheimer Disease: Emerging Issues in Neurology. *Neurology*. 2023;101(19):842-852. doi:10.1212/WNL.0000000000207757

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