

## PHARMACY POLICY STATEMENT

### Common Ground Healthcare Cooperative (CGHC)

<b>DRUG NAME</b>	<b>Kisunla (donanemab)</b>
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 (A $\beta$ ) 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  $\epsilon$ 4 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  $\epsilon$ 4 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.
2. Albert MS, DeKosky ST, Dickson D, et al. The diagnosis of mild cognitive impairment 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):270-279. doi:10.1016/j.jalz.2011.03.008
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. Anti-amyloid 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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