Utilization Review Policy 343B

POLICY: Neurology – Kisunla Utilization Management Medical Policy

- Kisunla™ (donanemb-azbt intravenous infusion – Lilly)

EFFECTIVE DATE: 11/15/2024
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: UCare Medicare Plans (UCare Medicare, UCare Medicare with M Health Fairview and North Memorial, EssentiaCare, Group Plans, MSHO, Connect + Medicare, UCare Your Choice)

OVERVIEW

Kisunla, an amyloid beta-directed antibody, is indicated for the treatment of **Alzheimer's disease**.[1] 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.

Disease Overview

An estimated 6.9 million Americans ≥ 65 years of age are living with Alzheimer's dementia in 2024, with 73% of these people ≥ 75 years of age.[2] The number and proportion of older adults who have mild cognitive impairment due to Alzheimer's disease is difficult to estimate; however, a rough approximation suggests that 5 to 7 million older Americans may have mild cognitive impairment due to Alzheimer's disease. People with mild cognitive impairment due to Alzheimer's disease have biomarker evidence of brain changes due to the disease in addition to subtle problems with memory and thinking. Biomarker evidence includes abnormal levels of amyloid beta as evidenced on positron emission tomography (PET) scans and in analysis of cerebrospinal fluid, and decreased metabolism of glucose as shown on PET scans. These cognitive problems may be noticeable to the individual family members and friends, but not to others, and they do not interfere with the person's ability to carry out everyday activities. The mild changes in cognitive abilities occur when the brain can no longer compensate for the damage and death of nerve cells due to Alzheimer's disease.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Kisunla. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are

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cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kisunla is recommended in those who meet the following criteria:

FDA-Approved Indications

1. Alzheimer's Disease.

Criteria. Approve for 1 year if the patient meets the following (A, B and C):

A) The patient has a clinical diagnosis of mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease **[documentation required]**; AND

B) The presence of amyloid beta pathology consistent with Alzheimer's disease has been confirmed **[documentation required]**; AND

C) The patient meets one of the following (i or ii):

- **i.** The patient is receiving the requested medication as part of a prospective comparative study **[documentation required]** AND the study is CMS-approved **[documentation required]**; OR
- **ii.** The patient is receiving the requested medication as part of a clinical trial **[documentation required]** AND the trial is supported by the National Institutes of Health (NIH) **[documentation required]**.

Dosing. Approve the following dosing: 700 mg administered as an intravenous infusion over approximately 30 minutes every four weeks for the first three doses, followed by 1400 mg every four weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kisunla is not recommended in the following situations:

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1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kisunla™ intravenous infusion [prescribing information]. Indianapolis, IN: Lilly; July 2024.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2024. Available at: https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf. Accessed on July 9, 2024.
3. Sims JR, Zimmer JA, Evans CD, et al, for the TRAILBLAZER-ALZ 2 Investigators. Donanemab in early symptomatic Alzheimer disease: The TRAILBLAZER-ALZ 2 randomized clinical trial. *JAMA*. 2023;330(6):512-527.
4. Andrews JS, Desai U, Kirson NY, et al. Disease severity and minimal clinically important differences in clinical outcome assessments for Alzheimer's disease clinical trials. *Alzheimers Dement.* 2019;5:354-363.
5. Mintun MA, Lo AC, Duggan Evans C, et al. Donanemab in early Alzheimer's disease. *N Engl J Med*. 2021;384(18):1691-1704.
6. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) 200.3. [Version Number 1, Effective date: 04/07/2022. Accessed July 25, 2024.
7. Centers for Medicare and Medicaid Services. Fact Sheet: CMS announces new details of plan to cover new Alzheimer's drugs. https://www.cms.gov/newsroom/fact-sheets/cms-announces-new-details-plan-cover-new-alzheimers-drugs - Issued 06/22/2023. Accessed February 22, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/31/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024

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