Utilization Review Policy 343A

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 Medicaid Plans (PMAP, Connect, MSC+, MnCare) and UCare Health Exchange Plans (individual and Family Plans)

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.

Clinical Efficacy

The current Kisunla efficacy information is insufficient to determine if the medication demonstrates any clinically meaningful benefits.

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. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Kisunla as well as the monitoring required for adverse events and long-term efficacy, approval requires Kisunla to be prescribed by a neurologist or gerontologist.

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Documentation: Documentation is required for use of Kisunla as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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1. **Alzheimer's Disease.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets EACH of the following (i through x):
     - **i.** Patient is ≥ 18 years of age and ≤ 85 years of age; AND
     - **ii.** Patient has a diagnosis of Alzheimer's disease with mild cognitive impairment or mild Alzheimer's dementia as demonstrated by 3 validated scales, one of which must be the MMSE (Mini Mental State Exam) AND
     - **iii.** Patient meets all of the following criteria (a, b, and c):
       - **a)** Patient has had magnetic resonance imaging (MRI) of the brain within the past 1 year **[documentation required]**; AND
       - **b)** The MRI showed both of the following (1 and 2):
         - **(1)** No prior cerebral hemorrhage greater than 1 cm in greatest diameter, no more than 4 microhemorrhages, no more than 1 area of superficial siderosis, no evidence of vasogenic edema, or severe white matter disease **[documentation required]**; AND
         - **(2)** Medical or neurological conditions, other than Alzheimer's disease, that may be contributing to the patient's cognitive impairment have been ruled out **[documentation required]**; AND
       - **c)** Patient has not had a stroke or transient ischemic attack (TIA) or seizures in the past 12 months; AND
     - **iv.** Patient meets one of the following (a or b):
       - **a)** 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 ARIA **[documentation required]**; OR
       - **b)** 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, if they are at higher risk for developing ARIA; AND
     - **v.** Patient has had a positive test for amyloid beta based on a Positron Emission Tomography (PET) scan or via cerebral spinal fluid (CSF) amyloid beta test **[documentation required]**; AND
     - **vi.** Patient does NOT have a clinically significant unstable psychiatric illness; AND
     - **vii.** Patient meets one of the following (a or b):

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a) Patient is NOT taking anticoagulant or antiplatelet agents (except aspirin for prevention of cardiovascular or thromboembolic events); OR

b) Patient is currently taking an anticoagulant and counseling has been provided that the combined use of Kisunla with an anticoagulant may increase the risk of cerebral macrohemorrhage and prescriber attests that the patient has shared in decision making to initiate Kisunla therapy; AND

Note: Anticoagulant or antiplatelet agents include Pradaxa (dabigatran capsules), Savaysa (edoxaban tablets), Eliquis (apixaban tablets), Xarelto (rivaroxaban tablets), warfarin, low-molecular-weight heparins (enoxaparin sodium injection, Fragmin [dalteparin sodium injection]), fondaparinux sodium injection, prasugrel hydrochloride tablets, clopidogrel tablets, or Brilinta (ticagrelor tablet).

viii. Prescriber attests that the patient and/or caregiver understands the risks and benefits of Kisunla therapy; AND

ix. Patient is not using in combination with any other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Leqembi); AND

x. The medication is prescribed by a neurologist or gerontologist.

B) Patient is Currently Receiving Kisunla. Approve for 6 months if the patient meets EACH of the following (i through viii):

i. Patient is ≥ 18 years of age; AND

ii. Patient has not progressed rapidly into moderate to severe Alzheimer's disease unless the prescriber provides published peer-reviewed clinical research supporting its continued use (rapid decline is defined as a 4-point reduction in a 6-month period on the MMSE, with an additional 1-point reduction in the following 6 months) **[documentation required]**; AND

iii. Patient is able to tolerate a Kisunla maintenance dose of 1,400 mg every 4 weeks; AND

iv. Patient meets the following (a, b, c, and d):

a) If the patient has received one infusion of Kisunla, the patient has had an MRI of the brain prior to the 2nd infusion of Kisunla to determine if the patient has developed amyloid related imaging abnormalities (ARIA) **[documentation required]**; AND

b) If the patient has received two infusions of Kisunla, the patient has had an MRI of the brain prior to the 3rd infusion of Kisunla to determine if the patient has developed amyloid related imaging abnormalities (ARIA) **[documentation required]**; AND

c) If the patient has received three infusions of Kisunla, the patient has had an MRI of the brain prior to the 4th infusion of Kisunla to determine if the patient has developed amyloid related imaging abnormalities (ARIA) **[documentation required]**; AND

d) If the patient has received six infusions of Kisunla, the patient has had an MRI of the brain prior to the 7th infusion of Kisunla to determine if the patient has developed ARIA **[documentation required]**; AND

v. If an MRI confirms ARIA, the patient meets ONE of the following (a or b):

a) Patient meets BOTH of the following (i and ii):

i. Patient has fewer than ten new incident microhemorrhages **[documentation required]**; AND

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ii. Patient has two or fewer focal areas of superficial siderosis (radiographic severe ARIA-H) **[documentation required]**; OR

b) Patient has had a clinical evaluation and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of amyloid related imaging abnormalities-hemosiderin deposition [ARIA-H]) prior to continuing treatment **[documentation required]**; AND

vi. Patient will discontinue treatment when reduction of amyloid plaques are reduced to minimal levels on amyloid PET imaging, defined as either of the following (a or b):

a) Level is <11 Centiloids on a single PET scan; OR

b) Level is 11 to <25 Centiloids on two consecutive PET scans; AND

vii. Patient is not using in combination with any other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Leqembi); AND

viii. The medication is prescribed by a neurologist or gerontologist.

Dosing. The dose of Kisunla is 700mg given intravenously over approximately 30 minutes every 4 weeks for the first 3 doses, followed by 1,400mg given every 4 weeks thereafter.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kisunla is not recommended in the following situations:

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/24/2024
UCare Update	Created Medicaid and Health Exchange specific policy as the Kisunla manufacturer (Lilly) participates in the Medicaid Drug	09/06/2024

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	Rebate Program. Pathway to coverage matches other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease.	
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024

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