Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Donanemab-azbt (Kisunla)	MP-RX-FP-166-25	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Donanemab-azbt (Kisunla**),** an amyloid beta-directed antibody approved by the Food and Drug Administration (FDA) for the treatment of Alzheimer's disease. According to its approved label, Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

Background Information

Kisunla was approved based on a multicenter, randomized, double-blind, placebo-controlled, 18 month phase 3 study (TRAILBLAZER-ALZ 2) that demonstrated a difference of 3 points from placebo in the primary endpoint of integrated Alzheimer's Disease Rating Scale (iADRS). A minimum clinically important difference (MCID) of 5 points has been suggested for mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) and 9 points for AD with mild dementia (Wessels 2022). Notably, the manufacturer changed the primary endpoint from the Clinical Dementia Rating – Sum of Boxes (CDR-SB) used in the phase 2 trial to the iADRS in the phase 3 study. The FDA did not agree with the change, stating, "We do not agree that a statistically significant treatment effect on the iADRS, unaccompanied by a valid statistically significant treatment effect on its two components [Alzheimer's Disease Assessment Scale – Cognitive (ADAS-Cog 13) subscale and Alzheimer's Disease Cooperative Study – instrumental Activities of Daily Living (ADCS-iADL) subscale], is acceptable for use as a primary efficacy assessment. Thus, the iADRS should not be used as your primary efficacy assessment." (FDA Briefing Document, June 2024). The CDR-SB was used as a secondary endpoint instead in the phase 3 trial. The CDR-SB change was statistically, though not clinically significant (-0.7 on 18-point scale) over 76 weeks (19 months). Minimum change of 1 point is considered clinically meaningful (Andrews 2019; Cohen 2022). However, in the new 2023 consensus recommendations from the American Academy of Neurology (AAN), the panel suggests that in the early symptomatic stages of AD, it is conceivable that a 0.5-point differential in the CDR-SB could manifest with substantive effects on daily life, for example, if distinctions (e.g., between mild forgetfulness and more moderate memory loss affecting daily activities) affect the ability to maintain employment or remain in a long-standing shared home (Ramanan 2023). According to the FDA briefing document, the FDA Peripheral and Central Nervous System Drugs Advisory Committee concluded that demonstrated changes may be significant to an individual patient and may increase over time, and subsequently, recommended traditional FDA approval.

The Kisunla trial enrolled individuals with confirmed evidence of tau pathology (low to high burden) on brain PET imaging. However, in the Sponsor Briefing Document, the manufacturer states, "The measurement of tau levels

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is not standardized and therefore could not be readily implemented in routine clinical practice. Moreover, access to tau imaging is not generally available even in clinical practice." The FDA Briefing Document describes this as an enrichment strategy to increase the proportion of participants who were likely to progress during the placebo-controlled period. Confirmation of tau pathology was not included in the prescribing label for Kisunla.

The phase 3 study allowed for cessation of donanemab once amyloid levels were reduced below a certain quantitative threshold on PET imaging. Per the FDA Briefing Document, "Although participants appeared to show benefit compared to the overall placebo arm after dosing was stopped, there is not an adequate comparator group and there is no information on outcomes in similar participants if they had continued dosing. There remains uncertainty regarding the optimal treatment regimen for monoclonal antibodies targeting aggregated amyloid once amyloid levels have been reduced to a level that corresponds with a negative visual read on PET." Labeling recommends to consider stopping medication once amyloid plaques are reduced to "minimal" levels on amyloid PET.

imaging. The 2023 AAN Antiamyloid Monoclonal Antibody Therapy for Alzheimer Disease guidance offered no consensus on the optimal duration of antiamyloid monoclonal antibody therapy (Ramanan 2023).

Serious safety concerns include amyloid-related imaging abnormalities (ARIA), which can be observed on magnetic resonance imaging (MRI) as brain edema or sulcal effusions (ARIA-E) or brain bleeding as microhemorrhage and superficial siderosis (ARIA-H). These events were the most serious safety issues in clinical trials. Overall incidence of ARIA with Kisunla was 37% compared to 15% in the placebo group. ARIA with hemorrhage (ARIA-H) was more common in those with ApoE4 (a genetic risk factor for developing Alzheimer's disease).

Frequency of ARIA (Sims 2023)

	Kisunla N = 860	Placebo N = 876	Difference
ARIA (total)	**37%**	**15%**	**22%**
ARIA-H (isolated)	**31%**	**14%**	**17%**
ApoE ε4 noncarrier	**19%**	**11%**	**8%**
ApoE ε4 heterozygote	**31%**	**11%**	**20%**
ApoE ε4homozygote	**50%**	**20%**	**30%**
ARIA-H (microhemmorhage)	**27%**	**13%**	**14%**
ARIA-H (superficial siderosis)	**16%**	**3%**	**13%**
Intracerebral hemmorhage >1 cm	**0.4%**	**0.2%**	**0.2%**
ARIA-E	**24%**	**2%**	**22%**
ARIA-E (asymptomatic)	**18%**	**2%**	**16%**
ARIA-E (symptomatic)	**6%**	**0.1%**	**5.9%**
ApoE ε4 noncarrier	**16%**	**0.8%**	**15.2%**
ApoE ε4 heterozygote	**23%**	**2%**	**21%**
ApoE ε4homozygote	**41%**	**3%**	**39%**

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In the placebo-controlled period, there were three ARIA-related deaths in the donanemab-treated group, including one death from cerebral hemorrhage in the setting of ARIA E and ARIA H, compared to none on placebo. In the all- donanemab pool, there was an additional death from ARIA and an additional death from intracerebral hemorrhage in the setting of ARIA E. Both of the deaths from intracerebral hemorrhage were in patients with findings consistent with cerebral amyloid angiopathy (CAA), which is a known risk factor for intracerebral hemorrhage, and in one case, the patient had symptoms mimicking stroke and was administered thrombolytic therapy.

In order to address the serious adverse effects concerning ARIA, Kisunla label recommends baseline brain MRI and periodic monitoring with MRI (e.g., prior to the 2nd, 3rd, 4th, and 7th doses). Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. If an individual experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms. Notably, Kisunla label requires a total of five MRIs, compared to lecanemab's (Leqembi) four. The requirement for the extra MRI scan was expected after Kisunla trials showed that an MRI prior to the second infusion led to a 25% reduction in serious ARIA cases.

Additionally, per the FDA label in the Radiographic Findings of Cerebral Amyloid Angiopathy (CAA) section, it states, "Neuroimaging findings that may indicate CAA include evidence of prior intracerebral hemorrhage, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for intracerebral hemorrhage. The presence of an ApoE ε4 allele is also associated with cerebral amyloid angiopathy. In Study 1 [phase 3 study], the baseline presence of at least 2 microhemorrhages or the presence of at least 1 area of superficial siderosis on MRI, which may be suggestive of CAA, were identified as risk factors for ARIA. Patients were excluded from enrollment in Study 1 for findings on neuroimaging of prior intracerebral hemorrhage greater than 1 cm in diameter, more than 4 microhemorrhages, more than 1 area of superficial siderosis, severe white matter disease, and vasogenic edema."

"Warnings and Precautions" for Kisunla label states, "additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with Kisunla." In the phase 3 study, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. One death from intracerebral hemorrhage occurred in a patient who had symptoms mimicking stroke and was administered thrombolytic therapy. As a result, the label includes a boxed warning stating that because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with Kisunla.

The Kisunla label includes boxed warnings for risk of ARIA caused by amyloid beta-directed monoclonal antibodies, including Kisunla, with possible serious and life-threatening events occurring. Furthermore, serious intracerebral

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hemorrhage greater than 1 cm have occurred in those treated with this class of drugs. The boxed warning includes recommendations to test for ApoE ε4 carrier status prior to drug initiation, as well as discussion with the patient of the risks of ARIA across genotypes and implications of genetic test results, since ApoE ε4 homozygotes have been found to have a higher incidence of ARIA compared to heterozygotes and noncarriers. Risks versus benefits of initiating therapy with Kisunla should be considered due to the serious adverse events associated with ARIA that could occur. Prescribers should also inform patients that if genotyping cannot be done, they can still be treated with Kisunla, although it is not known if they are at higher risk for ARIA since ApoE ε4 status cannot be determined. At the time of publication of these criteria, there are no FDA-authorized tests for the detection of ApoE ε4 alleles to identify at-risk patients. Current available tests may vary in accuracy and design according to the FDA label for Kisunla.

Several voluntary provider-enrolled patient registries have been created to collect real world data so that information can be collected on novel treatments for Alzheimer's disease, including the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET). Providers may obtain information about the ALZ-NET at www.alz-net.org or contact alz- net@acr.org. Of note, the Centers for Medicare and Medicaid Services (CMS) requires participation in their own nationwide, CMS-facilitated registry as part of their coverage requirements for monoclonal antibodies directed against amyoid for the treatment of AD.

Definitions

- Amyloid Related Imaging Abnormalities (ARIA) = Abnormalities observed in the brain on magnetic resonance imaging (MRI)
    - ARIA with edema (ARIA-E) = findings consistent with brain edema or sulcal effusions
    - ARIA with hemorrhage (ARIA-H) = findings consistent with microhemorrhage and superficial siderosis
- Clinical Dementia Rating (CDR) scale = Measure used to stage dementia in the clinical and research setting, comprising of 75 items related to cognition and function.
- Global Score (CDR-GS, or plainly, CDR) = Calculated score that provides an overall rating of dementia severity using six areas – Memory*, Orientation, Judgment/Problem Solving, Community Affairs, Home/Hobbies, and Personal Care
    - 0 = no dementia/normal
    - 0.5 = questionable cognitive impairment/very mild dementia
    - 1 = mild cognitive impairment/mild dementia
    - 2 = moderate dementia
    - 3 = severe dementia
- CDR Memory (M) Box Score = Considered the primary category within the CDR-GS rating tool. All other categories are secondary. Final CDR-GS score is based on an algorithm with the memory box score playing a significant role in the calculation.
- Sum of Boxes Score (CDR-SB) = Detailed quantitative general index across the six categories
    - 0 = no dementia/normal

  - 0.5 – 4.0 = questionable cognitive impairment
  - 0.5 – 2.0 = questionable impairment
  - 2.5 – 4.0 = very mild dementia
  - 4.5 – 9.0 = mild dementia
  - 9.5 – 15.5 = moderate dementia
  - 16.0 – 18.0 = severe dementia
- Integrated Alzheimer's Disease Rating Scale (iADRS) = Linear combination of ADAS-Cog 13 and ADCS-iADL. Score ranges from 0 to 144, with lower scores indicating greater disease severity. The iADRS was developed to assess function and cognition, and more sensitive to change and treatment effects in the early stages of the AD.
- Alzheimer's Disease Assessment Scale – Cognitive (ADAS-Cog 13) Subscale = The ADAS-Cog 13 is a cognitive assessment consisting of clinical ratings and cognitive tasks measuring disturbances of memory, language, and praxis. The scale ranges from 0 to 85, with higher scores indicating greater disease severity.
- Alzheimer's Disease Cooperative Study – instrumental Activities of Daily Living (ADCS-iADL) Subscale = The ADCS-ADL is a rater-administered questionnaire for informants that consists of 23 items. Informants are asked whether the patient attempted each item during the past 4 weeks and to rate the patient's performance level. The iADL is a subset consisting of 17 items measuring instrumental activities of daily living which are thought to be more sensitive at earlier stages of the disease. The iADL score ranges from 0 to 59, with lower scores indicating greater impairment.
- Mild cognitive impairment (MCI) related to AD = Stage categorized by symptoms of memory and/or other thinking problems that are not normal for the individual's age and education, but that usually do not interfere with his or her independence. Sometimes referred to as the symptomatic predementia phase of AD.
- Mini Mental State Examination (MMSE) = An 11-question tool used to assess mental status that tests five areas of cognitive function – Orientation, Registration, Attention/Calculation, Recall, and Language. Scale is a range from 0 to 30 with 0 being severe dementia and 30 is no dementia.

Other Uses

None.

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J0175	Injection, donanemab-azbt, 2 mg [Kisunla]

ICD-10	Description
G30.0-G30.9	Alzheimer's Disease

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Donanemab-azbt (Kisunla)

A. Criteria For Initial Approval

i. Kisunla is prescribed by, or in consultation with, a neurologist, geriatrician, neuropsychiatrist, or psychiatrist; **AND**

ii. Individual is 60 to 85 years of age (Sims 2023); **AND**

iii. Individual has a diagnosis of one of the following (Sims 2023):
   A. Mild cognitive impairment (MCI) due to Alzheimer's Disease (AD); **OR**
   B. Mild AD dementia;

AND

iv. Individual has had a gradual and progressive change in memory function for at least 6 months (Sims 2023); **AND**

v. Documentation is provided that individual has objective impairment in episodic memory according to memory tests [i.e., Free and Cued Selective Reminding Test, the Rey Auditory Verbal Learning Test, the California Verbal Learning Test, or the Logical Memory I and II of the Wechsler Memory Scale Revised (or other versions)] (Albert 2011); **AND**

vi. Documentation is provided that individual has a Clinical Dementia Rating (CDR)-Global score of 0.5 to 1.0 (KnightADRC 2024, Perneczky 2006); **AND**

vii. Documentation is provided that individual has a CDR Memory Box score ≥ 0.5 (KnightADRC 2024, O'Bryant 2008); **AND**

viii. Documentation is provided that individual has a Mini Mental State Examination (MMSE) score of 20 to 28 (inclusive) (Sims 2023; Perneczky 2006); **AND**

ix. Documentation is provided that individual has presence of amyloid beta based on one of the following diagnostic tests (Sims 2023; Jack 2018):
   A. PET imaging showing presence of amyloid beta; **OR**
   B. Presence of long form amyloid beta (i.e., Aβ1-42, Beta-amyloid [1-42], Abeta42) in the cerebrospinal fluid;

AND

x. Documentation is provided that individual has had a baseline MRI (within the past year) that does ***not*** show any of the following:

A. Presence of amyloid-related imaging abnormalities of edema or effusion (Label; Sims 2023); **OR**
B. More than 4 microhemorrhages (defined as 10 mm or less at the greatest diameter) (Label; Sims 2023); **OR**
C. A single macrohemorrhage >10 mm at the greatest diameter (Label; Sims 2023); **OR**
D. An area of superficial siderosis (Label; Sims 2023); **OR**
E. Evidence of vasogenic edema (Label; Sims 2023); **OR**
F. Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions; **OR**
G. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; **OR**
H. Space occupying lesions; **OR**
I. Brain tumors (except those diagnosed as meningiomas or arachnoid cysts and <1 cm at their greatest diameter);

AND

xi. MRI will be reviewed by the prescriber prior to the 2nd, 3rd, 4th, and 7th infusions (Label); **AND**
xii. MRI will be reviewed by the prescriber prior to the next dose if ARIA is suspected (Label); **AND**
xiii. The prescriber and individual (or caregiver) have discussed and acknowledged the potential safety risks of treatment, including risks of ARIA-H and ARIA-E (Label); **AND**
xiv. The prescriber and individual have discussed and acknowledged that individuals who are apolipoprotein E (ApoE) ε4 homozygotes (approximately 15% of individuals with AD) treated with Kisunla have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA compared to heterozygotes and non-carriers (Label).

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Donanemab-azbt (Kisunla) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when all of the following criteria is met:
   A. Individual does *not* have evidence of symptomatic moderate to severe ARIA-E; **AND**
   B. Documentation is provided that individual does *not* have evidence of moderate to severe ARIA-E based on MRI; **AND**
   C. Individual does *not* have evidence of symptomatic ARIA-H; **AND**
   D. Documentation is provided that individual does *not* have evidence of moderate to severe ARIA-H based on MRI; **AND**
   E. MRI will be reviewed by the prescriber prior to the next dose if ARIA is suspected; **AND**
   F. Based on the clinical judgement of the provider, the benefits of continuation outweigh the risks.

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C. Authorization Duration

i. Initial Approval Duration: 4 months
ii. Reauthorization Approval Duration: 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

I. Any medical or neurological condition, other than AD, that might be a contributing cause of the individual's cognitive impairment (Sims 2023); **OR**
II. History of transient ischemic attacks (TIA), stroke, or seizures within the past year; **OR**
III. Contraindications to brain MRI scanning (such as non-MRI compatible pacemaker/defibrillator or other implants) (Sims 2023) ; **OR**
IV. Evidence of other clinically significant lesions on brain MRI that indicate another cause of the individual's cognitive impairment (Sims 2023); **OR**
V. Uncontrolled bleeding disorder, including those with a platelet count <50,000; **OR**
VI. International normalized ratio [INR] >1.5 (Sims 2023); **OR**
VII. Any uncontrolled immunological disease or immunological disease requiring treatment with immunoglobulins, systemic monoclonal antibodies (or derivatives of monoclonal antibodies), systemic immunosuppressants, or plasmapheresis.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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Drug	Recommended Dosing Schedule
Kisunla (donanemab-azbt) 350 mg/20 mL solution	4 vials (80 mL) per 4 weeks
Exceptions	
None	

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception 3/17/2025	Elevance Health's Medical Policy adoption	N/A	4/2/2025

Revised: 07/20/2024