Kisunla (donanemab-azbt)
PAM – 083

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/02/2024
Revision Number	2	**Last Reviewed**	10/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	10/15/2027
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	10/18/2024

Overview

Medication: [1]	donanemab-azbt
Brand Name:	Kisunla™
Pharmacologic Category:	Humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody; amyloid beta-directed antibody
FDA-Approved Indication(s):	• 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, the population in which treatment was initiated in clinical trials. • Patient selection: confirm presence of amyloid beta pathology prior to initiating treatment.
How Supplied:	Single-dose vial, 350 mg/20 mL
Dosage and Administration:	**Intravenous Infusion (every 4 weeks)** / **Kisunla Dosage** Infusion 1 – 350 mg Infusion 2 – 700 mg Infusion 3 – 1,050 mg Infusion 4 and beyond – 1,400 mg
Benefit Category:	Medical

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES (ARIA)

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Kisunla™, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. ARIA can be fatal. Serious intracerebral hemorrhages > 1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. 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 treated with Kisunla™.

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES (ARIA)

ApoE ε 4 Homozygotes

Patients who are apolipoprotein E ε 4 (ApoE ε 4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including Kisunla™, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε 4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, the risk of ARIA across genotypes and the implications of genetic testing results should be discussed with patients. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with Kisunla™; however, it cannot be determined if they are ApoE ε 4 homozygotes and at higher risk for ARIA.

Consider the benefit of Kisunla™ for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment.

Descriptive Narrative

Alzheimer's disease (AD), a neurocognitive disorder, causes progressive cognitive deterioration and is characterized by beta-amyloid deposits and neurofibrillary tangles in the cerebral cortex and subcortical gray matter. Diagnosis is clinical; laboratory and imaging tests are usually done to look for specific findings that suggest Alzheimer's disease and to identify other treatable causes of dementia.

AD is the most common cause of dementia, accounting for 60 to 80 percent of dementias in older people. An estimated 6.7 million Americans aged 65 and older are living with Alzheimer's dementia today, and Alzheimer's disease remains the fifth-leading cause of death in the U.S.[2]

Currently approved treatments for treating various stages of dementia associated with AD include:

1. The cholinesterase inhibitors (donepezil, rivastigmine, and galantamine) and the N-methyl-D-aspartate (NMDA) receptor antagonist (memantine).
   - These drugs modestly improve cognitive function and memory in some patients.
2. Lecanemab-irmb (Leqembi®) is a recombinant humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta.
   - Leqembi® was initially approved under the accelerated approval pathway as a treatment for AD based upon evidence of efficacy from a change in a surrogate endpoint (e.g., amyloid reduction), considered as reasonably likely to predict clinical benefit.

- In July 2023, Leqembi® received full FDA approval based on results of the phase 3 trial that showed a change of 0.45 points on an 18-point scale in the Clinical Dementia Rating – Sum of Boxes (CDR-SB) over 18 months.[3]
    - As a note: clinical meaningfulness of this change is still unclear since a minimum change of 1 point on the CDR-SB scale is considered clinically significant.
- Leqembi® is also currently under investigation for pre-clinical AD (clinical trials identifier NCT04468659).[4]

3. Kisunla™ (donanemab-azbt) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against insoluble N-truncated pyroglutamate amyloid beta.
    - Kisunla™ was approved by the FDA on July 2, 2024 (regular approval).
    - It is the first and only amyloid plaque targeting-therapy with evidence to support stopping therapy when amyloid plaques are removed.
    - Lilly is currently recruiting study participants for a clinical trial evaluating Kisunla™ in early symptomatic Alzheimer's disease (clinical trials identifier NCT05508789).[5]

Amyloid Related Imaging Abnormalities (ARIA)

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Kisunla™, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E), and ARIA with hemosiderin deposition (ARIA-H). ARIA can occur spontaneously in patients with Alzheimer's disease (AD), particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy, such as pretreatment microhemorrhage or superficial siderosis. ARIA-H associated with monoclonal antibodies directed against aggregated forms of beta amyloid generally occurs in association with an occurrence of ARIA-E. ARIA-H of any cause and ARIA-E can occur together.

Monitoring for ARIA-E and ARIA-H

- Obtain recent (within one year) baseline brain magnetic resonance imaging (MRI) prior to initiating treatment with Kisunla™.
- Obtain brain MRI prior to the 2nd, 3rd, 4th, and 7th infusions.
- If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.

ARIA-E Management

- Recommendations for dosing interruptions in patients with ARIA-E depend on both clinical symptoms and radiographic severity.

- Review current prescribing information for dosing interruption recommendations, and use clinical judgment in considering whether to continue dosing in patients with recurrent ARIA-E.

ARIA-H Management

- Recommendations for dosing in patients with ARIA-H depend on both the type of ARIA-H and radiographic severity.
- Review current prescribing information for dosing interruption recommendations, and use clinical judgment in considering whether to continue dosing in patients with ARIA-H.

In patients who develop intracerebral hemorrhage greater than 1 centimeter (cm) in diameter during treatment with Kisunla™, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Resumption of dosing should be guided by clinical judgment.

ApoE ε4 Carrier Status and Risk of ARIA

Approximately 15 percent of Alzheimer's disease patients are apolipoprotein E ε4 (ApoE ε4) homozygotes. The risk of ARIA, including symptomatic and serious ARIA, is increased in ApoE ε4 homozygotes. Testing for ApoE ε4 status should be performed prior to initiation of treatment with Kisunla™ to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.

An FDA-authorized test for detection of ApoE ε4 alleles to identify patients at risk of ARIA if treated with Kisunla™ is not currently available. Currently available tests used to identify ApoE ε4 alleles may vary in accuracy and design.

Guidelines

The American Academy of Neurology (AAN) published guidelines on mild cognitive impairment (MCI) in 2001. A practice guideline update summary was published in January of 2018. Practice guidelines do not yet include anti-amyloid therapies such as Kisunla™ and will need to be updated to integrate these new therapies and treatment modalities.

Diagnostic Criteria and Rating Scales

Global CDR® Score (CDR-GS)

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	0.5	1	2	3
normal	very mild dementia	mild dementia	moderate dementia	severe dementia

Sum of Boxes Score (CDR-SB)

Detailed quantitative general index across the 6 categories.[6]

- 0 = no dementia/normal
- 0.5 – 4.0 = questionable cognitive impairment
  - 0.5 – 2.5 = questionable impairment
  - 3.0 – 4.0 = very mild dementia
- 4.5 – 9.0 = mild dementia
- 9.5 – 15.5 = moderate dementia
- 16.0 – 18.0 = severe dementia

Mini Mental State Examination (MMSE)

A tool used to assess cognitive function in older adults. It is not used on its own to diagnose dementia but combined with other factors (such as analysis of brain scans, a neurological exam, evaluation of medical history, etc.), it can be used as an indicator of dementia. It is scored on a 30-point scale, with items that assess orientation (temporal and spatial; 10 points), memory (registration and recall; 10 points), attention/concentration (5 points), language (verbal and written; 8 points), and visuospatial function (1 point).

While different cutoff points have been used across studies, scores $\leq$ 23 are most commonly regarded as abnormal and indicative of cognitive impairment. However, age, education, and race/ethnicity each appear to have significant effects on overall MMSE scores, suggesting that these demographic variables should be taken into account when evaluating individual patient performance.

Advantages of the MMSE are that it is easy to administer, and it only takes about 10 minutes to complete. Disadvantages of the test however include that it requires a certain level of education, which could make it less reliable (i.e., an educated person with dementia may be able to score above a 24, and a person with a sub-eighth grade level of education may score below 24 despite not having dementia, which could lead to a misdiagnosis). The MMSE is also not very sensitive to mild cognitive impairment or early dementia (someone in the beginning stages could still achieve a high score). [7]

MMSE Scoring Chart (score range and corresponding level of dementia)

- 24 and higher = Normal cognition; no dementia
- 19 to 23 = Mild dementia
- 10 to 18 = Moderate dementia
- 9 and lower = Severe dementia

Clinical dementia rating (CDR): 0, 0.5, 1, 2, 3					
The CDR® Dementia Staging Instrument is a 5-point scale. The necessary information to make each rating is obtained through a semi-structured interview of the patient and a reliable informant or collateral source (e.g., family member). [8]					
Impairment	None (0)	Questionable (0.5)	Mild (1)	Moderate (2)	Severe (3)
Memory	No memory loss or slight inconstant forgetfulness	Consistent slight forgetfulness; partial recollection of events	Moderate memory loss; more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
Orientation	Fully oriented	Fully oriented or slight difficulty with time relationships	Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere	Severe difficulty with time relationships; usually disoriented in time, often to place	Oriented to person only
Judgment and problem	Solves everyday problems and handles business and financial affairs well; judgment good in relation to past performance	Slight impairment to solving problems, similarities, differences	Moderate difficulty in handling problems, similarities, differences; social judgment usually maintained	Severely impaired in handling problems, similarities, differences; social judgment usually impaired	Unable to make judgments or solve problems
Community affairs	Independent function at usual level in job, shopping, volunteer and social groups	Slight impairment in these activities	Unable to function independently at these activities though may still be engaged in some; appears normal to casual inspection	No pretense of independent function outside of home; appears well enough to be taken to functions outside of family home	No pretense of independent function outside of home; appears too ill to be taken to functions outside a family home
Home and hobbies	Life at home, hobbies, intellectual interests well maintained	Life at home, hobbies, intellectual interests slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly maintained	No significant function in home
Personal care	Fully capable of self-care	Fully capable of self-care	Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence

Criteria

NOTE: Pursuant to the terms of the CMS National Coverage Determination:
1) Monoclonal antibodies directed against amyloid that are approved for the treatment of Alzheimer's disease (AD) *based upon evidence of efficacy from a change in a surrogate endpoint (e.g., amyloid reduction)* considered as reasonably likely to predict clinical benefit may be covered in a randomized clinical trial under an investigational new drug (IND) application.
2) Monoclonal antibodies directed against amyloid that are approved for the treatment of AD b*ased upon evidence of efficacy from a direct measure of clinical benefit* (such as Leqembi® and Kisunla™) may be covered in CMS approved prospective comparative studies. Study data for CMS approved prospective comparative studies may be collected in a registry.[9]

Prior authorization is required.

Kisunla® is considered medically necessary when **ALL** of the following are met:
1. Clinical diagnosis of Alzheimer's disease (AD) [either mild cognitive impairment (MCI) stage or mild dementia stage]; **AND**
2. Member is 60 to 85 years old; **AND**
3. Presence of beta-amyloid plaques verified by **AT LEAST ONE** of the following (a or b):
    a. Positron emission tomography (PET) scan; **AND/OR**
    b. Cerebrospinal fluid (CSF) testing; **AND**
4. Documented baseline brain magnetic resonance imaging (MRI) performed within the past 12 months prior to the start of therapy; **AND**
5. In addition to baseline brain MRI prior to the initiation of treatment, member will also have an MRI prior to the 2nd, 3rd, 4th, and 7th infusions; **AND**
6. Member has no history of transient ischemic attacks (TIA), stroke, or seizures within the past 12 months; **AND**
7. Objective evidence of cognitive impairment prior to therapy initiation; **AND**
8. Member meets both of the following:
    a. Has had a gradual and progressive change in memory function for at least 6 months; **AND**
    b. Has a score of 20 to 28 (inclusive) on the Mini-Mental State Examination (MMSE); **AND**
9. Other known causes of dementia have been ruled out (e.g., vascular dementia, Parkinson's disease dementia, Lewy body dementia, frontotemporal dementia); **AND**
10. Kisunla™ is not used in combination with other therapies directed at amyloid beta (e.g., Leqembi®); **AND**
11. Prescribed by, or in consultation with, a neurologist, geriatrician, or geriatric psychiatrist; **AND**
12. Request meets **ONE** of the following (a or b):
    a. Regimen prescribed does not exceed one intravenous infusion every four (4) weeks at the following doses: 350 mg (infusion 1); 700 mg (infusion 2); 1,050 mg (infusion 3); 1,400 mg (infusion 4 and beyond); **OR**
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Kisunla® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Member is 60 to 85 years of age; **AND**
3. Documentation of positive clinical response to therapy, as demonstrated by improvement OR stabilization in baseline cognitive scoring (as assessed by the prescribing provider); **AND**
4. Member has received (or will receive, if applicable) a brain MRI prior to the 2nd, 3rd, 4th, and 7th infusions. If symptoms suggestive of ARIA are experienced, clinical evaluation should be performed; **AND**
5. Based on the clinical judgment of the provider, the benefits of continuation outweigh the risks; **AND**
6. Kisunla® is not used in combination with other therapies directed at amyloid beta (e.g., Leqembi™); **AND**
7. Prescribed by, or in consultation with, a neurologist, geriatrician, or geriatric psychiatrist; **AND**
8. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 1,400 mg every 4 weeks (infusion 4 and beyond); or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	IV infusion (once every 4 weeks) • Infusion 1: 350 mg • Infusion 2: 700 mg • Infusion 3: 1,050 mg • Infusion 4: 1,400 mg	IV infusion (once every 4 weeks) • 1,400 mg (if member is on infusion #4 or later)

IV - intravenous

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J0175	Injection, donanemab-azbt, 2 mg

ICD-10	Description
G30	Alzheimer's disease
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified

NDC (and strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
00002-9401-01 (350 mg/20 mL)	Eli Lilly and Company (00002)	2 mg	1	EA	175

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Kisunla™ prescribing information (07/2025). Eli Lilly and Company: Indianapolis, IN. Available online: kisunla.lilly.com/hcp. Accessed July 31, 2026.

[2] 2023 Alzheimer's Disease Facts and Figures. Alzheimers Dement. 2023 Apr;19(4):1598-1695. PMID 36918389.

[3] A Study to Confirm Safety and Efficacy of Lecanemab in Participants with Early Alzheimer's Disease (Clarity AD). ClinicalTrials.gov identifier: NCT03887455. www.clinicaltrials.gov/study/NCT03887455. Updated April 7, 2026. Accessed July 31, 2026.

[4] AHEAD 3-45 Study: A Study to Evaluate Efficacy and Safety of Treatment with Lecanemab in Participants with Preclinical Alzheimer's Disease and Elevated Amyloid and Also in Participants with Early Preclinical Alzheimer's Disease and Intermediate Amyloid. ClinicalTrials.gov identifier: NCT04468659. Updated June 4, 2026. www.clinicaltrials.gov/study/NCT04468659. Accessed July 31, 2026.

[5] A Study of Donanemab (LY3002813) in Participants With Early Symptomatic Alzheimer's Disease (TRAILBLAZER-ALZ 5). ClinicalTrials.gov identifier: NCT05508789. www.clinicaltrials.gov/study/NCT05508789. Updated July 16, 2026. Accessed July 31, 2026.

[6] Lynch CA, Walsh C, et al. The clinical dementia rating sum of box score in mild dementia. Dement Geriatr Cogn Disord. 2006;21(1):40-3. Epub 2005 Oct 25. PMID: 16254429.

[7] Mendez MF. Mental status scales to evaluate cognition. Wilterdink JL, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 5, 2026.

[8] Wolk DA, Dickerson BC. Clinical features and diagnosis of Alzheimer disease. Wilterdink JL, ed. UpToDate. Waltham, MA: UpToDate, Inc. www.uptodate.com. Accessed August 5, 2026.

[9] Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease (CAG-00460N). Medicare Coverage Database. Available online: www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx. Accessed August 5, 2026.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/16/2026	CAC	Annual review. Updated references. 7/1/2025: FDA changed recommended dosing regimen to one with a lower incidence of ARIA. Updated Overview and Criteria. Updated criteria to include new dosing and to more closely align with requirements for other amyloid beta-directed antibodies.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee