AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Kisunla™ (donanemab-azbt) IV (J0175) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

- **Titrated dosing: Week 0 (Initial Dose):** IV 350 mg once, **Week 4:** IV 700 mg once, **Week 8:** IV 1,050 mg once, **Week 12 and onward:** IV 1,400 mg once every 4 weeks; until amyloid plaques are reduced to minimal levels on amyloid PET imaging
- **NOTE:** The following dose schedule, used in the original clinical trials and the FDA approved dose prior to July 2025, may be associated with a higher risk of amyloid-related imaging abnormalities compared to the titrated dosing regimen

(Continued on next page)

- **Alternative dosing (off label):** 700 mg once every 4 weeks for the first 3 doses (2 vials), followed by 1400 mg (4 vials) once every 4 weeks thereafter until amyloid plaques are reduced to minimal levels on amyloid PET imaging
- Kisunla is available as a single-dose vial, 350 mg/20 mL solution, administered intravenously (IV) over approximately 30 minutes
- 350 mg/20 mL; 1 vial = 175 billable units

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months (6 infusion doses only)

- ❑ Prescribed by or in consultation with a neurologist
- ❑ Member must be 60-85 years of age or older
- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ALL** the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5 to 1.0
  - ❑ CDR Memory Box score of at least ≥ 0.5
- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ONE** of the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Mini-Mental State Exam (MMSE) score of 22-28
  - ❑ Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13] score of ≥ 18
  - ❑ Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI]
  - ❑ Montreal Cognitive Assessment (MoCA) score of greater than or equal to 16
- ❑ Member has/is experiencing signs and symptoms of mild cognitive impairment characterized by skills that affect memory (i.e., inability to make sound decisions, judge time, sequence, steps needed to complete a complex task) **(must submit chart note documentation)**
- ❑ Provider must submit chart notes supporting that other differential diagnoses have been ruled out (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy)
- ❑ Provider must submit documentation of beta-amyloid protein deposition, as evidenced by **ONE** of the following:
  - ❑ Positive amyloid positron emission tomography (PET) scan
  - ❑ Cerebrospinal fluid (CSF) measurement positive assessment Aß (1-42)

(Continued on next page)

- ❑ Provider must submit documentation that meets **ONE** of the following requirements regarding apolipoprotein E ε4 (ApoE ε4) testing and its implications for treatment:
  - ❑ Member 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
  - ❑ Genotype testing has not been performed and the prescriber has informed the patient that it cannot be determined if they are apolipoprotein E ε4 (ApoE ε4) homozygotes and, therefore, if they are at higher risk for developing ARIA
- ❑ Provider attests that counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and member and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea and vomiting
- ❑ A brain magnetic resonance imaging (MRI) will be reviewed prior to the 2nd, 3rd, 4th and 7th infusions
- ❑ Member must have undergone a recent (within the last year) brain magnetic resonance imaging (MRI) demonstrating **ALL** the following **(must submit MRI results)**:
  - ❑ No brain hemorrhage > 1 cm within the past year
  - ❑ No more than 4 brain microhemorrhages (defined as 10mm or less at the greatest diameter)
  - ❑ No evidence of localized superficial siderosis
  - ❑ No evidence of vasogenic edema
- ❑ Member does **NOT** have any relevant brain hemorrhage, bleeding disorder, cerebrovascular abnormalities, or recent (within the prior year) cardiovascular condition (e.g., unstable angina, myocardial infarction, advanced CHF, or clinically significant conduction abnormalities)
- ❑ Member has **NOT** had a stroke, transient ischemic attack (TIA) or unexplained loss of consciousness in the past 12 months
- ❑ Member is **NOT** currently receiving anti-platelet agents (with the exception of prophylactic aspirin), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin)
- ❑ Member does **NOT** have impaired renal or liver function
- ❑ Member has **NOT** had a clinically significant and unstable psychiatric illness in the past six months
- ❑ Kisunla™ will **NOT** be used concurrently with other anti-amyloid immunotherapies (i.e., lecanemab, aducanumab)

Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ALL** the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5 to 1.0
  - ❑ CDR Memory Box score of at least ≥ 0.5

(Continued on next page)

- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ONE** of the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Mini-Mental State Exam (MMSE) score of 22-28
  - ❑ Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13] score of $\geq$ 18
  - ❑ Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI]
  - ❑ Montreal Cognitive Assessment (MoCA) score of greater than or equal to 16
- ❑ Member has **NOT** progressed to moderate or severe dementia
- ❑ Provider continues to monitor member for the occurrence of any medical or neurological conditions (other than Alzheimer's disease) that may be a contributing cause to the member's cognitive impairment
- ❑ Member will discontinue treatment when reduction of amyloid plaques is reduced to minimal levels on amyloid PET imaging, defined as either **ONE** of the following **(must submit documentation)**:
  - ❑ Level is < 11 centiloids on a single PET scan
  - ❑ Level is 11 to < 25 centiloids on two consecutive PET scans
- ❑ Member has received the follow-up MRI for monitoring of Amyloid Related Imaging Abnormalities edema (ARIA-E) or hemosiderin (ARIA-H) at the following timeframes **(must submit results)**:
  - ❑ Pre-2nd infusion
  - ❑ Pre-3rd infusion
  - ❑ Pre-4th infusion
  - ❑ Pre-7th infusion
- ❑ Member must meet **ONE** of the following:
  - ❑ Results from MRI must meet **ONE** of the following for members with radiographic evidence of amyloid **related imaging abnormalities edema (ARIA-E**):
    - ❑ Member has had no new ARIA-E
    - ❑ Member has mild ARIA-E on MRI **AND** ARIA-E is asymptomatic (no clinical symptoms)
    - ❑ Member has had moderate or severe ARIA-E on MRI **AND** ARIA-E is asymptomatic (no clinical symptoms) **AND** the ARIA-E is stable
    - ❑ Member has had mild, moderate or severe ARIA-E on MRI **AND** ARIA-E resulted in mild, moderate or severe clinical symptoms **AND** the ARIA-E is stable
  - ❑ Results from MRI must meet **ONE** of the following for members with radiographic evidence of amyloid **related imaging abnormalities microhemorrhage (ARIA-H)**:
    - ❑ Member has had 1 to 4 new incident microhemorrhage(s) **AND** microhemorrhages are asymptomatic (no clinical symptoms)
    - ❑ Member has had 5 to 9 new incident microhemorrhages **AND** microhemorrhages are asymptomatic (no clinical symptoms) **AND** the microhemorrhages have been stabilized
    - ❑ Member has had 1 to 9 new incident microhemorrhages **AND** microhemorrhages resulted in mild, moderate or severe clinical symptoms **AND** the microhemorrhages have been stabilized

(Continued on next page)

- ❑ Results from MRI must meet **ONE** of the following for members with radiographic evidence of amyloid **related imaging abnormalities superficial siderosis (ARIA-H)**:
  - ❑ Member has had no new incident areas of superficial siderosis
  - ❑ Member has had 1 new incident area of superficial siderosis **AND** superficial siderosis is asymptomatic (no clinical symptoms)
  - ❑ Member has had 2 new incident areas of superficial siderosis **AND** superficial siderosis is asymptomatic (no clinical symptoms) **AND** the superficial siderosis has been stabilized
  - ❑ Member has had 1 to 2 new incident areas of superficial siderosis **AND** superficial siderosis resulted in mild, moderate or severe clinical symptoms **AND** the superficial siderosis has been stabilized

Appendix/General Information

ARIA MRI Classification Criteria

ARIA Type	Radiographic Severity		
	Mild	**Moderate**	**Severe**
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortical white matter in one location < 5cm	FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring <10 cm	FLAIR hyperintensity measuring > 10cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	>2 focal areas of superficial siderosis

(Continued on next page)

Recommendations for Dosing Interruptions in Patients with Amyloid Related Imaging Abnormalities (ARIA)

Table 1: Dosing Recommendations for Patients with ARIA-E

Clinical Symptom Severity[a]	ARIA-E Severity on MRI		
	Mild	Moderate	Severe
Asymptomatic	May continue dosing at current dose and schedule	Suspend dosing[b]	Suspend dosing[b]
Mild	May continue dosing based on clinical judgment	Suspend dosing[b]	
Moderate or Severe	Suspend dosing[b]		

[a] Mild: discomfort noticed, but no disruption of normal daily activity.
Moderate: discomfort sufficient to reduce or affect normal daily activity.
Severe: incapacitating, with inability to work or to perform normal daily activity.

[b] Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.

Table 2: Dosing Recommendations for Patients with ARIA-H

Clinical Symptom Severity	ARIA-H Severity on MRI		
	Mild	Moderate	Severe
Asymptomatic	May continue dosing at current dose and schedule	Suspend dosing[a]	Suspend dosing[b]
Symptomatic	Suspend dosing[a]	Suspend dosing[a]	

[a] Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.

[b] Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgment when considering whether to continue treatment or permanently discontinue KISUNLA.

In patients who develop intracerebral hemorrhage greater than 1 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.

(Continued on next page)

Appendix/General Information

Dementia Rating Scales

Type of dementia rating scale	Description	Rate
Clinical Dementia Rating-Global score (CDR-GS)	Useful for characterizing and tracking a patient's level of impairment/dementia	• 0 = normal • 0.5 = very mild dementia • 1 = mild dementia • 2 = moderate dementia • 3 = severe dementia
Mini-Mental State Exam (MMSE)	Series of questions asked by a health professional designed to test a range of everyday mental skills.	• 25 to 30 suggest normal cognition • 20 to 24 suggests mild dementia • 13 to 20 suggests moderate dementia • less than 12 indicates severe dementia
Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS- Cog-13, ADAS-Cog 14]	Series of questions scaled for five cognitive domains such as immediate memory, delayed memory, attention, language, visuospatial ADAS-Co 14 include executive function	• ADAS-Cog 13 scale range from to 0 to 85 • ADAS-Cog 14 range from 0 to 90 • Higher scores indicate greater cognitive impairment
Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS- ADL- MCI]	Series of questions to assess the performance of basic and instrumental activities of daily living.	• ADCS-ADL-MCI range from 0 to 53 • Lower score indicate poorer functional performance
Montreal Cognitive Assessment (MoCA)	Series of questions to assess multiple cognitive domains such as orientation, memory, language, attention, visuospatial and executive function	• Normal: 26 and above • Mild Cognitive Impairment: 19-25 • Mild Dementia: 11-21 *16.2= MoCA average score for Alzheimer's Disease

(Continued on next page)

References:

1. 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.
2. Mintun MA, Lo AC, Duggan Evans C, et al. Donanemab in early Alzheimer's disease. N Engl J Med. 2021;384(18):1691-1704.
3. Kisunla™ intravenous infusion [prescribing information]. Indianapolis, IN: Lilly; July 2024.
4. Liu KY, Schneider LS, Howard R. The need to show minimum clinically important differences in Alzheimer's disease trials. *Lancet Psychiatry*. 2021;8(11):1013-1016.
5. Arvanitakis Z, Shah RC, Bennett DA. Diagnosis and management of dementia: a review. JAMA. 2019;322(16):1589-1599.
6. Langa, LM, Levine DA. The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review.
7. Lin GA, Whittington MD, Wright A, Agboola F, Herron-Smith S, Pearson SD, Rind DM. Beta-Amyloid Antibodies for Early Alzheimer's Disease: Effectiveness and Value; Draft Evidence Report. Institute for Clinical and Economic Review, December 22, 2022.

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.
Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee:** ~~9/26/2024; 5/22/2025;~~ **9/25/2025**
REVISED/UPDATED/REFORMATTED: ~~10/15/2024; 6/18/2025;~~ **10/16/2025**