kisunla®
(donanemab-azbt)
injection for intravenous use
350 mg/20 mL

A Lilly Medicine

Not an actual patient.

# PATIENT SUPPORT AND PRIOR AUTHORIZATION GUIDE

## INDICATION

Kisunla is indicated for the treatment of Alzheimer's disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

## SELECT IMPORTANT SAFETY INFORMATION

**WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES**

**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 usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events 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 being treated with Kisunla.**

**ApoE ε4 Homozygotes: Patients who are apolipoprotein E ε4 (ApoE ε4) homozygotes 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 ε4 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 implications of genetic testing results should be discussed with patients.**

**Consider the benefit for the treatment of Alzheimer's disease and risk of ARIA when deciding to treat with Kisunla.**

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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# INTRODUCTION

Lilly is committed to providing you with support for Kisunla. This **Patient Support and Prior Authorization Guide** has been developed to assist with:

- Understanding Centers for Medicare & Medicaid Services (CMS) coverage
- Completing a Prior Authorization (PA) for Kisunla
- Accessing and enrolling patients in Lilly Support Services™ for Kisunla

This guide is for informational purposes only and is not intended to provide reimbursement or legal advice. Each healthcare provider or healthcare entity is responsible for determining the appropriate codes, coverage, and payment for individual patients. Lilly does not guarantee third-party coverage or payment for denied claims.

Providers should always verify coverage prior to initiating therapy and determine the appropriate codes on a case-by-case basis. Insurance coverage, coding, claims filing, and reimbursement vary by setting of care and payer type.

**If you have questions or need assistance, contact Lilly Support Services for Kisunla at 1-800-LillyRx (1-800-545-5979)**

## SELECT IMPORTANT SAFETY INFORMATION

**Hypersensitivity: Kisunla is contraindicated** in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis.

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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# ALL MEDICARE AND MEDICARE ADVANTAGE PLANS ARE REQUIRED TO COVER AMYLOID-TARGETING THERAPIES (ATTS), INCLUDING KISUNLA, UNDER COVERAGE WITH EVIDENCE DEVELOPMENT (CED)[1,2,8]

## The National Coverage Determination (NCD) on monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) is binding for all Medicare plans and contractors[11]

**Covered population[1]:**

- Patients who have a clinical diagnosis of MCI due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD

**Coverage criteria—drugs in class that receive traditional FDA approval[1]:**

- Patient must be enrolled in Medicare
- Patients must have a diagnosis of MCI due to AD or mild AD dementia, with confirmed presence of amyloid beta pathology consistent with AD in the brain
- Physician must participate in a qualifying registry* with an appropriate clinical team and follow-up care†

**For more information on the CMS National Patient Registry for monoclonal antibodies directed against amyloid for the treatment of AD, visit https://qualitynet.cms.gov/alzheimers-ced-registry**

***For more information on qualifying registries, visit https://www.cms.gov/medicare/coverage/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad**

†Prescribing clinicians or their staff shall submit at first baseline treatment via the dedicated CMS CED data submission portal and every 6 months for up to 24 months (5 total assessments).[3]

MCI=mild cognitive impairment.

## SELECT IMPORTANT SAFETY INFORMATION

### Amyloid-Related Imaging Abnormalities (ARIA)

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur. ARIA can be fatal. When present, reported symptoms associated with ARIA may include, but are not limited to, headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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# CMS REGISTRY CODING REQUIREMENTS

Based on the CED requirements, CMS requires additional codes and modifiers as part of a claim for treatment with Kisunla.[4] These may include:

- **Diagnosis codes:** Must include both Z00.6 (to denote clinical research participation) AND an appropriate AD diagnosis code (see page 5 for more information)[4,5]
- **Registry modifiers:** Must include either Q0 or Q1 (to note participation in a registry)[4,6]
- **Registry number:** If the patient is enrolled in the CMS National Patient Registry, please use NCT 06058234. If the patient is enrolled in a different CMS-approved CED registry, please use the assigned ClinicalTrials.gov number as appropriate[3,4,7]

Institutional claims using the UB-04/CMS-1450 form require the following information[4]:

- **Type of bill:** 12X, 13X, or 85X
- **Revenue code:** 0636
- **Condition code:** 30

**Scan the code to view the Kisunla Billing and Coding Guide https://kisunla.lilly.com/hcp/support-resources**

## SELECT IMPORTANT SAFETY INFORMATION

### Risk Factors for ARIA and Intracerebral Hemorrhages (ICH)

- **ApoE ε4 Carrier Status:** The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein E ε4 (ApoE ε4) homozygotes.
- Recommendations for management of ARIA do not differ based on ApoE ε4 carrier status. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA.

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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# ASSISTING WITH A PA REQUEST FOR KISUNLA

Many insurers will require a PA to access Kisunla. In requesting access for your patients, please keep in mind that insurers generally have plan-specific PA forms and processes. Please refer to the plan for specific requirements.

### Medicare Advantage plans

In addition to enrolling patients in a qualifying patient registry (see "CMS Registry Coding Requirements" on page 4), offices may be required to complete a PA form and/or an Appeals Letter.

### Commercial insurance

For eligible, commercially insured patients with prescription, a PA will likely need to be completed and sent to the payer to determine a coverage decision.

Although individual plan requirements will vary, the following information is frequently requested when submitting a PA for Kisunla.

**Medical information that may be required for a PA[8]**

| | |
|---|---|
| **Indication** | Kisunla is indicated for the treatment of Alzheimer's disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. |
| **Dosage and Administration** | Administer Kisunla as an intravenous infusion over approximately 30 minutes every four weeks as follows: 350 mg for Infusion 1, 700 mg for Infusion 2, 1050 mg for Infusion 3, 1400 mg for Infusion 4 and beyond. Kisunla must be diluted prior to administration.[8] |
| **Continuation of therapy guidance** | Consider stopping dosing with Kisunla based on reduction of amyloid plaques to minimal levels on amyloid PET imaging.[8*†] |

*In the Phase 3 clinical trial, dosing was stopped in response to observed effects on amyloid imaging. Completion of active treatment was based on amyloid PET levels measured at week 24, week 52, and week 76. If amyloid plaque level was <11 Centiloids on a single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, subjects taking Kisunla were eligible to switch to placebo. Amyloid PET values may increase after treatment with Kisunla is stopped. There is no data beyond the 76-week duration of TRAILBLAZER-ALZ 2 to guide whether additional dosing with Kisunla may be needed for longer-term clinical benefit.[8]

†For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[9]

PET=positron emission tomography.

## SELECT IMPORTANT SAFETY INFORMATION

### Risk Factors for ARIA and Intracerebral Hemorrhages (ICH) (continued)

- **Radiographic Findings of Cerebral Amyloid Angiopathy (CAA):** Neuroimaging findings that may indicate CAA include evidence of prior ICH, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for ICH. The presence of an ApoE ε4 allele is also associated with CAA.
- 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 for findings on neuroimaging of prior ICH >1 cm in diameter, >4 microhemorrhages, >1 area of superficial siderosis, severe white matter disease, and vasogenic edema.

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# RELEVANT INFORMATION WHEN COMPLETING A PA FOR KISUNLA

## Clinical/coding information that may be requested for Kisunla‡

| | | | |
|---|---|---|---|
| **ICD-10 Diagnosis Code[5]** | **CMS Registry Modifier** | | **For CMS billing, providers must include Z00.6 in addition to one of the AD diagnosis codes listed in the chart.**<br>Providers should use current ICD-10 codes to report a patient's diagnosis on claim submissions. The list of ICD-10 diagnosis codes provided on the left may be reasonably related to a diagnosis within the product's approved label. Other codes may be appropriate.<br>Correct coding is the responsibility of the provider submitting a claim for the item or service. Please see FDA-approved indication for Kisunla and check with the payer to verify coding or special billing requirements.<br>There are no specific codes currently available for a diagnosis of MCI due to Alzheimer's disease. G31.84 should be used in addition to a G30-code to indicate a diagnosis of AD with MCI. |
| | **Z00.6** | **Encounter for examination for normal comparison and control in clinical research program** | |
| | **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 | |
| | **Mild Cognitive Impairment** | | |
| | G31.84 | MCI of uncertain or unknown etiology | |
| **HCPCS Level II Code[4]** | J0175: Injection, donanemab-azbt, 2mg | | |
| **National Drug Codes (NDCs)[8]** | 10-digit NDC: 0002-9401-01<br>11-digit NDC: 00002-9401-01 | | 350 mg/20 mL single-dose vial, individually packaged in a carton |
| **IV Infusion Administration Codes[10]** | 96413: Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug | | |
| | 96365: IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour | | |

**Scan the code to view the Kisunla Billing and Coding Guide https://kisunla.lilly.com/hcp/support-resources**

‡These codes are not intended to be promotional or to encourage or suggest a use of drug that is inconsistent with US FDA-approved use. The codes provided are not exhaustive and additional codes may apply. Listed codes may require a higher level of specificity when reporting for individual patients. Please note that providers are responsible for selecting appropriate codes for any particular claim based on the patient's diagnosis, the items and services that are furnished, and any specific payer requirements. It is advisable to contact your local payer with regard to local payment policies.

HCPCS=Healthcare Common Procedure Coding System; ICD=International Classification of Diseases; IV=intravenous.

## SELECT IMPORTANT SAFETY INFORMATION

### Risk Factors for ARIA and Intracerebral Hemorrhages (ICH) (continued)

- **Concomitant Antithrombotic or Thrombolytic Medication:** In Study 1, the majority of exposures to antithrombotic medications were to aspirin. The number of events and the limited exposure to non-aspirin antithrombotic medications limit definitive conclusions about the risk of ARIA or ICH in patients taking antithrombotic medications. Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (eg, tissue plasminogen activator) to a patient already being treated with Kisunla. One fatal ICH occurred in a patient taking Kisunla in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent in Study 1, and one fatal intracerebral hemorrhage occurred in the setting of ARIA and the use of a thrombolytic agent in Study 2.
- Consider whether ischemic stroke symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with Kisunla, because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke.
- Caution should be exercised when considering the use of Kisunla in patients with factors that indicate an increased risk for ICH and in particular for patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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# LILLY SUPPORT SERVICES FOR KISUNLA IS COMMITTED TO HELPING PATIENTS NAVIGATE THEIR TREATMENT JOURNEY WITH KISUNLA

**Lilly Support Services for Kisunla is a free support program that can partner with your patients to help them stay on track and feel supported to**

- Better understand insurance coverage, complete treatment costs, and saving options*
- Know what to expect when starting on Kisunla and different steps they might expect during treatment
- Navigate infusion and safety monitoring requirements across sites of care
- Access customized support from registered nurses and resources along their treatment journey

***Governmental beneficiaries excluded, terms and conditions apply.**

**For more information, scan the code to visit https://kisunla.lilly.com/hcp/support-resources or call Lilly Support Services at 1-800-LillyRx (1-800-545-5979)**

## SELECT IMPORTANT SAFETY INFORMATION

### ARIA Monitoring and Dose Management Guidelines

- Baseline brain MRI and periodic monitoring with MRI are recommended prior to the 2nd, 3rd, 4th, and 7th infusions. Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. If a patient 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.
- Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity. Depending on ARIA severity, use clinical judgment in considering whether to continue dosing, interrupt treatment, or permanently discontinue Kisunla. See Prescribing Information for additional dosing considerations.

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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# KISUNLA SAVINGS CARD

## Eligible commercially insured patients with coverage for Kisunla may pay as little as $0 per infusion† of Kisunla.

†**Governmental beneficiaries excluded.** Eligibility required, terms and conditions apply. Savings subject to monthly and annual limits. Card eligibility and terms and conditions may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. **PROGRAM IS NOT INSURANCE.** Review full terms and conditions at **https://kisunla.lilly.com/hcp/support-resources#savingscard**.

**Resident of the US or Puerto Rico aged 18 years or older**

**Must have an eligible prescription for Kisunla consistent with FDA-approved product labeling**

**Must have commercial drug insurance plan and have coverage for Kisunla but your insurance does not cover the full cost of Kisunla**

## SELECT IMPORTANT SAFETY INFORMATION

### Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with Kisunla. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy.

### Infusion-Related Reactions (IRR)

IRRs were observed with Kisunla with the majority occurring within the first 4 infusions. Most IRRs occurred during the infusion or within 30 minutes after completion of the infusion, however some have occurred hours after an infusion. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, flushing, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure. In the event of an IRR, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Consider pre-treatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing.

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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# ENROLLING PATIENTS IN LILLY SUPPORT SERVICES FOR KISUNLA

## Help your patients get started on Kisunla by enrolling them in Lilly Support Services for Kisunla

### 1 Select Enrollment Option

Patients can be enrolled using either the digital enrollment portal or by fax/printed Enrollment Form.

### 2 Complete the Entire Enrollment Form

Please review Enrollment Form in detail to ensure all required information is completed to prevent delays in your patients starting treatment. Ensure that patient HIPAA (Health Insurance Portability and Accountability Act) authorization and an HCP signature is captured on the Enrollment Form.

- To obtain patient HIPAA authorization, patients can sign the Enrollment Form in the office, Lilly Support Services for Kisunla can send patients a link to sign electronically, or patients can call Lilly Support Services to provide HIPAA authorization verbally.

### 3 Submit Completed Enrollment Form

Submit to Lilly Support Services via the digital enrollment portal or fax to 1-844-731-2697.

**Please see the Patient Support Enrollment Form, which can be downloaded at https://kisunla.lilly.com/assets/pdf/kisunlaenrollmentform.pdf or scan the code to the left**

## SELECT IMPORTANT SAFETY INFORMATION

### Adverse Reactions

The most common adverse reactions reported in ≥5% of patients treated with Kisunla and ≥2% higher than placebo: ARIA-H microhemorrhage, ARIA-E, ARIA-H superficial siderosis, headache, and IRRs.

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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## IMPORTANT SAFETY INFORMATION FOR Kisunla® (donanemab-azbt)

**WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES**

**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 usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events 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 being treated with Kisunla.**

**ApoE ε4 Homozygotes: Patients treated with this class of medications, including Kisunla, who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 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.**

**Consider the benefit for treating Alzheimer's disease and risk of ARIA when deciding to treat with Kisunla.**

Kisunla is **contraindicated** in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis.

### Amyloid-Related Imaging Abnormalities (ARIA)

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur. ARIA can be fatal. When present, reported symptoms associated with ARIA may include, but are not limited to, headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

In Study 1, safety was assessed in patients who received Kisunla Dosing Regimen 1 (n=853) compared to those who received placebo (n=874). In Study 2, the effect of different dosing regimens of Kisunla on ARIA was assessed, including in patients who received Kisunla Dosing Regimen 2 (n=212).

Incidence of ARIA

A lower incidence of ARIA was observed with Dosing Regimen 2 as compared to Dosing Regimen 1. Therefore, Dosing Regimen 2 is the recommended dosage for Kisunla.

In Study 1, symptomatic ARIA-E occurred in 6% of patients through 18 months of treatment with Kisunla.

Clinical symptoms associated with ARIA resolved in approximately 85% of those patients.

Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed with Kisunla: 36%, 24%, and 31% of patients treated with Kisunla, respectively compared to 14%, 2%, and 13% of patients on placebo. There was no increase in isolated ARIA-H for Kisunla vs placebo.

In Study 2, symptomatic ARIA-E occurred in 3% of patients and symptomatic ARIA-H occurred in less than 1% of patients through 12 months of treatment with Kisunla. Clinical symptoms associated with ARIA-E resolved in approximately 67% of patients at 12 months. Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed in 29%, 16%, and 25% of patients treated with Kisunla.

Incidence of Intracerebral Hemorrhage (ICH)

ICH >1 cm in diameter was reported in 0.5% of patients treated with Kisunla vs 0.2% on placebo in Study 1 and in 1% of patients treated with Kisunla in Study 2. Fatal events of ICH have been observed in patients taking Kisunla.

**Please click for additional Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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## IMPORTANT SAFETY INFORMATION FOR Kisunla® (donanemab-azbt) (CONT'D)

### Amyloid-Related Imaging Abnormalities (ARIA) (Cont'd)

Risk Factors for ARIA and ICH

*ApoE ε4 Carrier Status*

The risk of ARIA, including symptomatic and serious ARIA, is increased in ApoE ε4 homozygotes.

Recommendations for management of ARIA do not differ based on ApoE ε4 carrier status. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. An FDA-authorized test for detection of ApoE ε4 alleles is not currently available. Currently available tests may vary in accuracy and design.

*Radiographic Findings of Cerebral Amyloid Angiopathy (CAA)*

Neuroimaging findings that may indicate CAA include evidence of prior ICH, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for ICH. The presence of an ApoE ε4 allele is also associated with CAA.

The baseline presence of at least 2 microhemorrhages or the presence of at least 1 area of superficial siderosis on magnetic resonance imaging (MRI), which may be suggestive of CAA, were identified as risk factors for ARIA. Patients were excluded from enrollment in Study 1 and Study 2 for findings on neuroimaging of prior ICH >1 cm in diameter, >4 microhemorrhages, >1 area of superficial siderosis, severe white matter disease, and vasogenic edema.

*Concomitant Antithrombotic or Thrombolytic Medication*

In Study 1, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed. The majority of exposures to antithrombotic medications were to aspirin. The number of events and the limited exposure to non-aspirin antithrombotic medications limit definitive conclusions about the risk of ARIA or ICH in patients taking antithrombotic medications.

One fatal ICH occurred in a patient taking Kisunla in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent in Study 1, and one fatal intracerebral hemorrhage occurred in the setting of ARIA and the use of a thrombolytic agent in Study 2. 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, and additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (eg, tissue plasminogen activator) to a patient being treated with Kisunla. Advise patients to carry information that they are being treated with Kisunla.

Caution should be exercised when considering the use of Kisunla in patients with factors that indicate an increased risk for ICH and in particular for patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

Monitoring and Dose Management Guidelines

Obtain a recent baseline brain MRI prior to initiating treatment and prior to the 2nd, 3rd, 4th, and 7th infusions. Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. If a patient 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.

Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity. Depending on ARIA severity, use clinical judgment in considering whether to continue dosing, interrupt treatment, or permanently discontinue Kisunla. See Prescribing Information for additional dosing considerations.

### Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with Kisunla. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy.

**Please click for full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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## IMPORTANT SAFETY INFORMATION FOR Kisunla® (donanemab-azbt) (CONT'D)

### Infusion-Related Reactions (IRR)

IRRs were observed with Kisunla with the majority occurring within the first 4 infusions. Most IRRs occurred during the infusion or within 30 minutes after completion of the infusion, however some have occurred hours after an infusion. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, flushing, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure.

In the event of an IRR, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Consider pre-treatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing.

**Adverse Reactions:** The most common adverse reactions reported in ≥5% of patients treated with Kisunla and ≥2% higher than placebo were ARIA-H microhemorrhage, ARIA-E, ARIA-H superficial siderosis, headache, and IRRs.

Kisunla (donanemab-azbt) injection for intravenous use is available as a 350 mg/20 mL single-dose vial.

**Please click for full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

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**References: 1.** CMS.gov. Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (CAG-00460N). Accessed March 11, 2025. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=305 **2.** CMS.gov. Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD). Accessed March 11, 2025. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1 **3.** CMS.gov. Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD). Accessed July 4, 2024. https://www.cms.gov/medicare/coverage/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad **4.** Centers for Medicare & Medicaid Services. National patient registry for new Alzheimer's drugs: things to know for clinicians. Published July 6, 2023. Accessed February 20, 2024. https://qualitynet.cms.gov/files/64a7151bd15911001c695b32?filename=Provider%20Factsheet%20Alzheimers%20Treatment.pdf **5.** Centers for Disease Control and Prevention. ICD-10-CM tabular list of diseases and injuries (2024). National Center for Health Statistics. Published July 5, 2023. Accessed February 20, 2024. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2024 **6.** Centers for Medicare & Medicaid Services. New HCPCS modifiers when billing for patient care in clinical research studies. CMS Manual System, pub 100-04 Medicare claims processing: transmittal 1418. Published January 18, 2008. Accessed February 20, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1418cp.pdf **7.** Brocato-Simons P, Hakim R; Centers for Medicare & Medicaid Services. Mandatory reporting of national clinical trial (NCT) identifier numbers on Medicare claims – Qs & As. Updated October 31, 2014. Accessed February 20, 2024. https://www.cms.gov/medicare/coverage/coverage-with-evidence-development/downloads/mandatory-clinical-trial-identifier-number-qsas.pdf **8.** Kisunla (donanemab-azbt). Prescribing Information. Lilly USA, LLC. **9.** Navitsky M, Joshi AD, Kennedy I, et al. Standardization of amyloid quantitation with florbetapir standardized uptake value ratios to the Centiloid scale. *Alzheimers Dement*. 2018;14(12):1565-1571. **10.** Centers for Medicare & Medicaid Services. Medicare program; revisions to payment policies under the physician fee schedule, clinical laboratory fee schedule, access to identifiable data for the Center for Medicare and Medicaid Innovation Models & other revisions to Part B for CY 2015. *Fed Regist*. 2014;79(219):67548-68010. **11.** CMS.gov. National Coverage Determination (NCD) 200.3 – Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD). Accessed August 19, 2025. https://www.cms.gov/files/document/r11692NCD.pdf

**Please click for full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**

kisunla® (donanemab-azbt) injection for intravenous use 350mg/20mL

A Lilly Medicine

Not an actual patient.

# HELPFUL REMINDERS

Keep in mind that patients with Medicare coverage must meet certain eligibility criteria per the National Coverage Determination (see page 4 for more information)

Be sure to include the appropriate ICD-10 codes directly on the PA (see page 6 for billing codes and pertinent information)

Remember that Lilly Support Services for Kisunla is here to help your patients

Your eligible, commercially insured patients with coverage for Kisunla may be eligible for the Kisunla Savings Card Program. **Governmental beneficiaries excluded, terms and conditions apply.**

For further assistance, please contact **Lilly Support Services for Kisunla** at **1-800-LillyRx (1-800-545-5979)**

**Please click for full Important Safety Information and full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide for Kisunla.**



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