kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Kisunla (donanemab-azbt)

Infusion Training Module

Your guide to preparing and administering the Kisunla infusion

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 rarely can occur. 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, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.

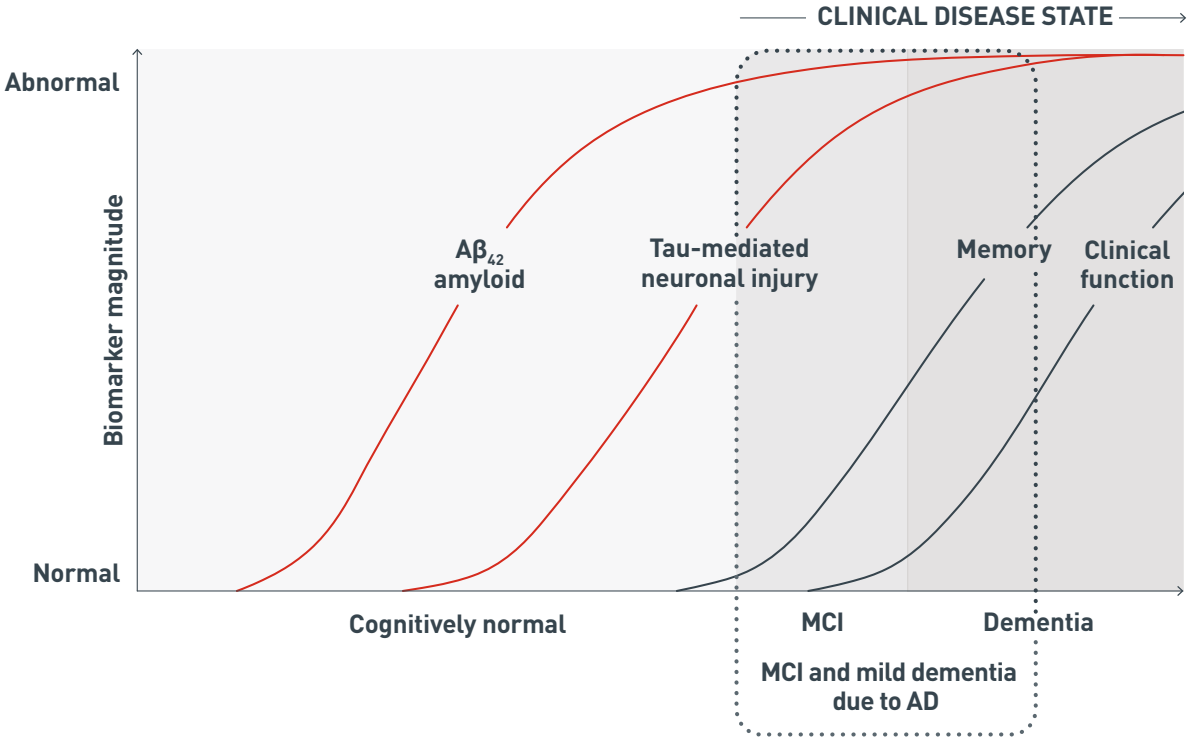
Consider the benefit for the treatment of Alzheimer's disease and risk of ARIA when deciding to treat with Kisunla.

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

NEXT

Amyloid, a key biomarker, represents an opportunity to treat early and slow disease progression in Alzheimer's disease (AD)[1]

BIOMARKER CHANGES IN ALZHEIMER'S DISEASE[2]



- Disease-modifying therapies (DMTs) target amyloid plaques to help slow disease progression[1]
- Amyloid plaques may begin to accumulate in the brain **approximately 20 years before symptoms present**[1]
- Acting early could give patients with early symptomatic AD an opportunity to benefit from DMTs[1]

Modified from Jack CR Jr, Knopman DS, Jagust WJ, et al. Tracking pathophysiological processes in Alzheimer's disease: an updated hypothetical model of dynamic biomarkers. *Lancet Neurol*. 2013;12(2):207-216.

Aβ=amyloid beta; MCI=mild cognitive impairment.

Hypothetical model of dynamic biomarkers of the AD pathological cascade, beginning with the abnormal accumulation of amyloid and the subsequent accumulation of tau, which leads to MCI and eventually dementia.[2]

AD progresses across a continuum of stages[3]

STAGES OF AD

PRECLINICAL AD
No symptoms but possible biological changes in the brain

MCI DUE TO AD
Very mild symptoms that may not interfere with everyday activities

MILD DEMENTIA DUE TO AD
Symptoms interfere with some everyday activities

MODERATE DEMENTIA DUE TO AD
Symptoms interfere with many everyday activities

SEVERE DEMENTIA DUE TO AD
Symptoms interfere with most everyday activities

Patients in the MCI and mild dementia stages of AD are potential candidates for amyloid-targeting therapies.[4]

Although these arrows are of equal size, the stages of the AD continuum are not equal in duration.

MCI=mild cognitive impairment; AD=Alzheimer's disease.

A Phase 3 study that assessed disease progression in early symptomatic Alzheimer's disease (AD) by reducing amyloid plaques[4,5]

ASSESSED IN 2 POPULATIONS[4,5]

Overall population (N=1736)

Low-medium tau population (N=1182)
Subset of overall population

- TRAILBLAZER-ALZ 2 had dual primary analysis populations. The study was powered to test the results of Kisunla (donanemab-azbt) in the low-medium tau (low tau to medium tau=earlier neuropathology) population[4,5*]
- It also allowed enrollment of high tau participants so Kisunla could be tested in the overall population (the low-medium tau population plus high tau participants)[4,5]

ELIGIBILITY[4]

- Confirmed presence of amyloid pathology
- AD with MCI or mild dementia

PRIMARY ENDPOINT[4]

- Change in iADRS score from baseline to 76 weeks (impact on cognitive and functional decline)

TREATMENT PERIOD[4]

- 1:1 randomization to Kisunla (n=860) or placebo (n=876) treatment arms at week 0
- Treated until amyloid plaques reached a minimal level[†] (assessed with amyloid PET scans at 24, 52, and 76 weeks), discontinuation, or study completion (76 weeks)[5]

DOSING AND ADMINISTRATION[4]

- Administered via once-monthly (Q4W) IV infusion (for up to 72 weeks)
- Kisunla: Q4W 700 mg, increased to 1400 mg at fourth infusion
- Placebo: Q4W
- ARIA-monitoring MRI before infusions 1, 2, 3, 4, and 7

*There were 2 primary analysis populations based on tau PET imaging with flortaucipir: 1) low-medium tau level population (SUVR of ≥1.10 and ≤1.46), and 2) combined population of low-medium plus high tau (SUVR >1.46).[4]

[†]In the protocol, if the amyloid plaque level was <11 Centiloids on a single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, the patient was eligible to be switched to placebo.[5]

For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[6]

STAGES OF AD

ARIA=amyloid-related imaging abnormalities; iADRS=integrated Alzheimer's Disease Rating Scale; IV=intravenous; MCI=mild cognitive impairment; MRI=magnetic resonance imaging; PET=positron emission tomography; Q4W=every 4 weeks; SUVR=standardized uptake value ratio.

AMYLOID PLAQUES

SELECT IMPORTANT SAFETY INFORMATION

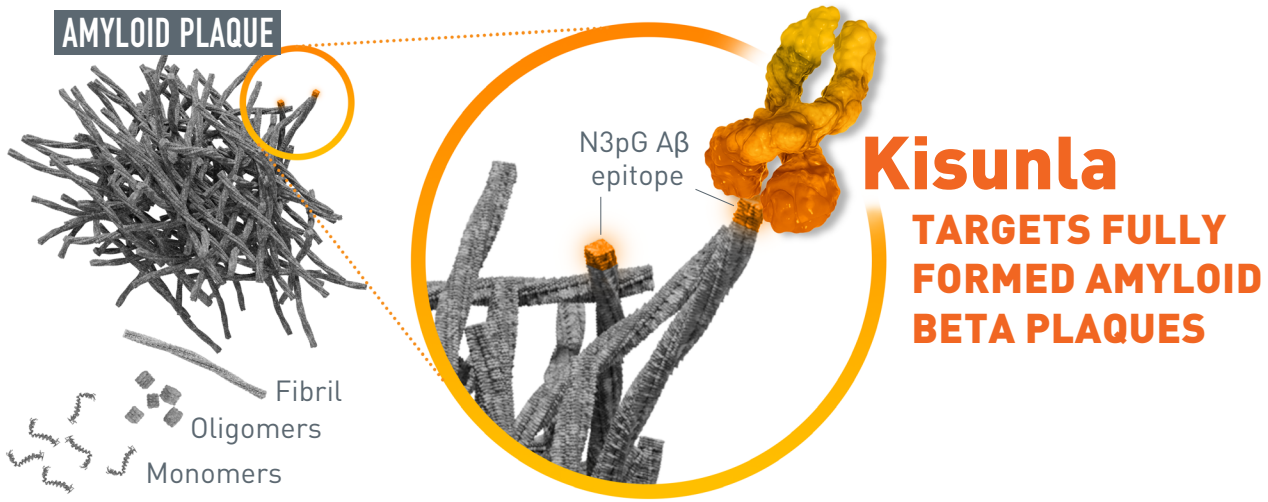
Risk Factors for ARIA and Intracerebral Hemorrhages (ICH)

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.

In Study 1, 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.

Kisunla targets fully formed amyloid beta plaques[4]

Kisunla is a humanized IgG1 monoclonal antibody directed against insoluble N-truncated pyroglutamate found in amyloid beta plaques in the brain—a defining feature of Alzheimer's disease (AD).[4]



IgG1=immunoglobulin gamma 1; N3pG=N-terminal, third amino acid, pyroglutamate formation; Aβ=amyloid beta.

Modified from Drolle H, Hane F, Lee B, et al. Atomic force microscopy to study molecular mechanisms of amyloid fibril formation and toxicity in Alzheimer's disease. *Drug Metab Rev.* 2014;46(2):207-223.

TRIAL DESIGN

KEY EFFICACY DATA

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.

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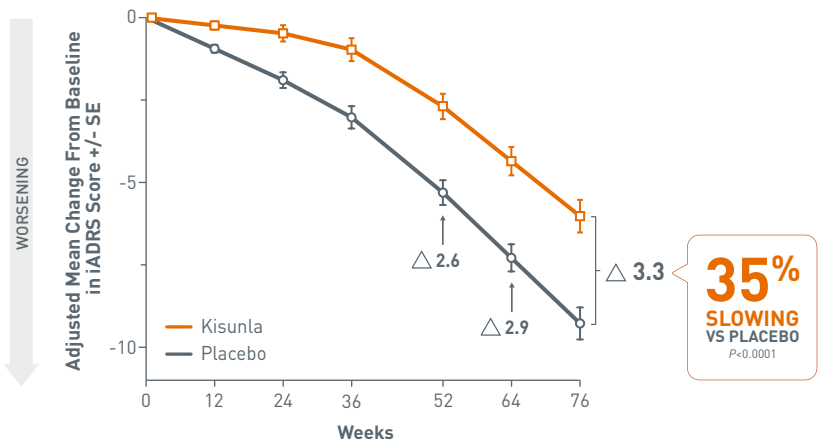
Kisunla gives you the power to help slow cognitive and functional decline in patients with early symptomatic Alzheimer's disease (AD)[4,5,7]

Testing for tau pathology is not required per the Prescribing Information or for CMS reimbursement.[4]

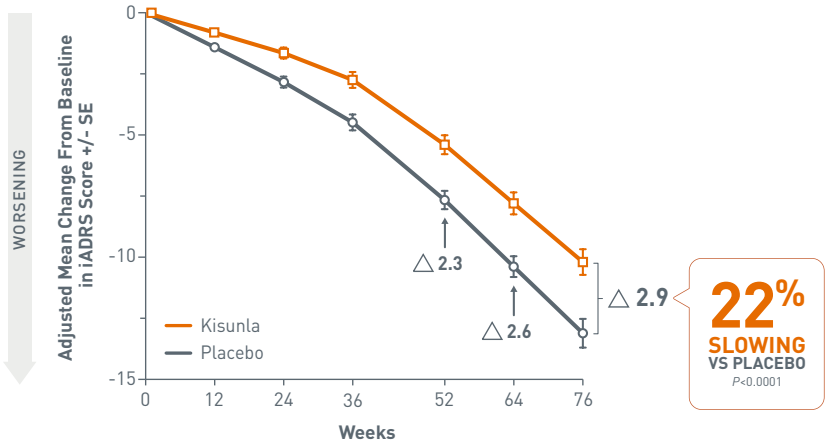
LOW-MEDIUM TAU POPULATION: iADRS CHANGE FROM BASELINE THROUGH 76 WEEKS[4,5,7,a,b]



No. of Participants							
Kisunla	533	517	487	459	441	406	418
Placebo	560	549	526	506	474	447	444

[a]Assessed using NCS2 analysis.[5]
[b]Mean baseline Kisunla: 105.92; mean baseline placebo: 105.95.[5]

OVERALL POPULATION: iADRS CHANGE FROM BASELINE THROUGH 76 WEEKS[4,5,7,a,b]



No. of Participants							
Kisunla	775	752	712	665	636	579	583
Placebo	824	805	767	738	693	651	653

[a]Assessed using NCS2 analysis.[5]
[b]Mean baseline Kisunla: 104.55; mean baseline placebo: 103.82.[5]

ABOUT KISUNLA

iADRS scores range from 0 to 144 with lower scores indicating greater impairment.[4]

AMYLOID PLAQUE REDUCTION

CMS=Centers for Medicare & Medicaid Services; iADRS=integrated Alzheimer's Disease Rating Scale; NCS2=natural cubic spline with 2 degrees of freedom; SE=standard error.

SELECT IMPORTANT SAFETY INFORMATION

Amyloid-Related Imaging Abnormalities (ARIA)

Kisunla can cause ARIA-E, which can be observed on magnetic resonance imaging (MRI) as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with Alzheimer's disease, particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy, such as pretreatment microhemorrhage or superficial siderosis. ARIA-H generally occurs with ARIA-E.

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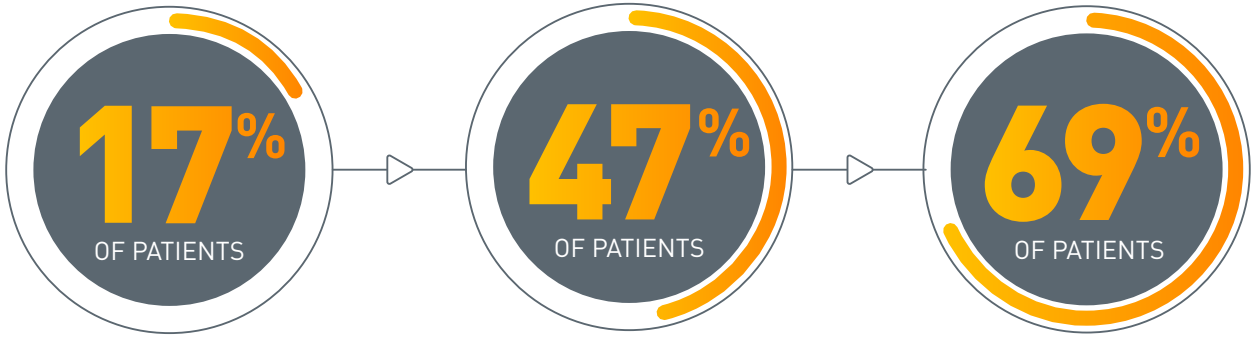
Nearly half of patients were able to stop treatment* by 1 year[4]

Kisunla was stopped based on removal of amyloid plaques to minimal levels on amyloid PET imaging in TRAILBLAZER-ALZ 2.[4]

PERCENTAGE OF PATIENTS IN THE OVERALL POPULATION ACHIEVING STOPPING CRITERIA* AT KEY TIME POINTS[4,8†]



*In the protocol, if the amyloid plaque level was <11 Centiloids on a single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, the patient was eligible to be switched to placebo. Amyloid PET values may increase after treatment with Kisunla is stopped. There are no data beyond the 76-week duration of the clinical trial to guide whether additional dosing with Kisunla may be needed for longer-term clinical benefit.[4]

For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[6]

†The mean baseline amyloid levels for patients treated with Kisunla were 103.5 Centiloids for the overall population, and 102.4 Centiloids for the low-medium tau population.[5]

PET=positron emission tomography.

KEY EFFICACY DATA | SAFETY PROFILE

SELECT IMPORTANT SAFETY INFORMATION

Amyloid-Related Imaging Abnormalities (ARIA) (cont'd)

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. 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 addition to ARIA, intracerebral hemorrhage (ICH) >1 cm in diameter has occurred in patients treated with Kisunla.

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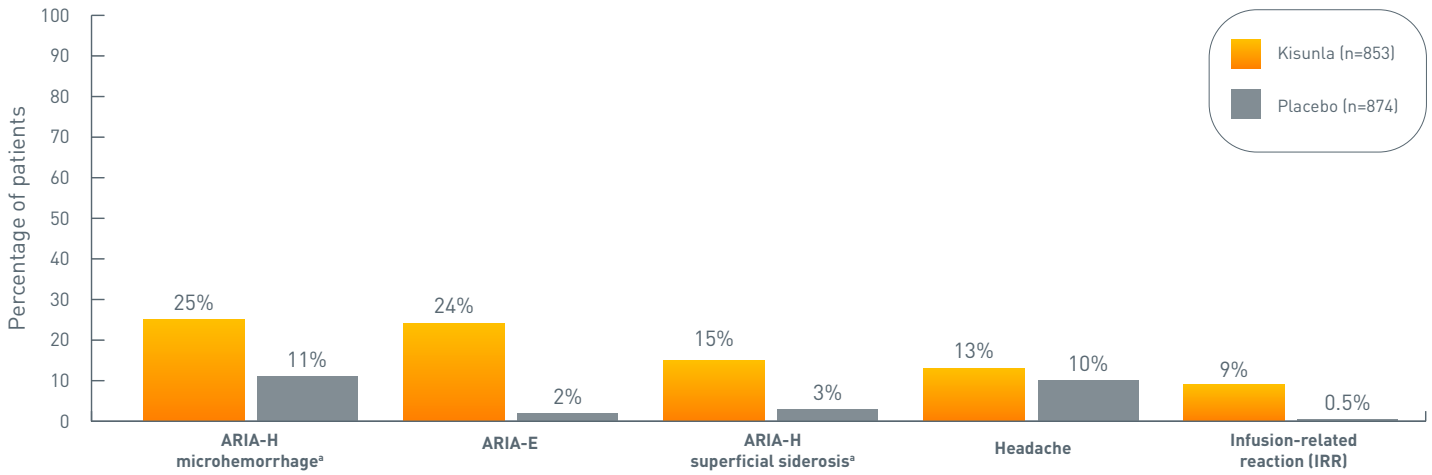
The safety of Kisunla was studied in more than 1900 patients in clinical trials[4*]

ADVERSE REACTIONS REPORTED IN ≥5% OF PATIENTS TREATED WITH KISUNLA AND ≥2% HIGHER THAN PLACEBO IN TRAILBLAZER-ALZ 2[4]



- ARIA-E (edema) includes brain edema or sulcal effusions[4]
- ARIA-H (hemosiderin deposition) most commonly includes microhemorrhage and superficial siderosis[4]

Thirteen percent of patients on Kisunla discontinued treatment due to adverse reactions vs 4% on placebo. The most common adverse reaction leading to discontinuation was infusion-related reaction (4% of patients on Kisunla vs 0% on placebo).[4]

[a]As assessed by MRI. A participant could have both microhemorrhage and superficial siderosis.[4]
*1912 patients with Alzheimer's disease (AD) received Kisunla once monthly for ≥6 months.[4]
ARIA=amyloid-related imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition; MRI=magnetic resonance imaging.

AMYLOID PLAQUE REDUCTION | SAFETY CONSIDERATIONS

SELECT IMPORTANT SAFETY INFORMATION

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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 rarely can occur. 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, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.

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

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Safety Considerations

AMYLOID-RELATED IMAGING ABNORMALITIES (ARIA)

- ARIA is a potential side effect associated with amyloid-targeting therapies, including Kisunla, and may occur when these therapies reduce amyloid plaques in the brain that have been accumulating for years. ARIA is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. Fatal events of intracerebral hemorrhage in patients taking Kisunla have been observed. 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[4,9]
- There are 2 types of ARIA detected on an MRI scan in patients with Alzheimer's disease (AD)[4]:
  - ARIA-H, for hemosiderin deposition, refers to areas of bleeding in the brain or the lining of the brain
  - ARIA-E, for edema, refers to swelling of the brain
- 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[4]
- Patients should have an MRI to monitor for ARIA prior to infusions 1, 2, 3, 4, and 7. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated[4]
- Enhanced clinical vigilance for ARIA by the prescriber, infusion center staff, and patient is recommended during the first 24 weeks[4]
- If ARIA is observed, the prescriber may change dosing based on clinical symptoms and radiographic severity. See Prescribing Information for additional dosing considerations[4]
- ARIA can occur at any time during treatment, and patients can have more than one episode, but the majority of cases occurred early and were asymptomatic[4]

SAFETY PROFILE

SAFETY CONSIDERATIONS (cont'd)

SELECT IMPORTANT SAFETY INFORMATION

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

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

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Safety Considerations (cont'd)

HYPERSENSITIVITY REACTIONS

- Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with Kisunla[4]
- Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy[4]
- Kisunla is contraindicated in patients with a history of serious hypersensitivity to donanemab-azbt or to any of the excipients of Kisunla[4]

INFUSION-RELATED REACTIONS (IRR)

- Signs and symptoms of IRR include chills, erythema, nausea/vomiting, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure[4]
- The majority of IRRs occurred within the first 4 infusions of Kisunla, although they can occur at any time. In clinical trials, infusion reactions occurred during infusion or within 30 minutes post-infusion. Observe the patient post-infusion for a minimum of 30 minutes[4]
- 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. Pretreatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing may be considered[4]

SAFETY CONSIDERATIONS

KISUNLA DOSING

SELECT IMPORTANT SAFETY INFORMATION

Risk Factors for ARIA and Intracerebral Hemorrhages

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

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Dosing Schedule[4]

1 MONTHLY INFUSION

30-MINUTE DURATION

Once-monthly Kisunla is the first and only FDA-approved ATT with dosing instructions that allow for limited-duration treatment[4*†]

- The recommended dosage of Kisunla is 700 mg every 4 weeks for 3 infusions, then 1400 mg every 4 weeks
- Kisunla is an IV infusion administered over approximately 30 minutes. Observe the patient for at least 30 minutes after the infusion for infusion-related and hypersensitivity reactions
- If an infusion is missed, resume administration every 4 weeks at the scheduled dose as soon as possible
- Consider stopping dosing based on removal of amyloid plaques to minimal levels consistent with a visually negative amyloid PET scan[‡]

*In the Phase 3 clinical trial, dosing was stopped in response to observed effects on amyloid imaging. Amyloid PET values may increase after treatment with Kisunla is stopped. There are 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.[4]

Obtain recent baseline brain MRI prior to initiating treatment. Perform an MRI prior to infusions 2, 3, 4, and 7. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated. 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.[4] See Prescribing Information for additional dosing considerations.

[†]In clinical trials, completion of active treatment was guided by 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.[4]
[‡]For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[6]

ARIA=amyloid-related imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition; ATT=amyloid-targeting therapy; IV=intravenous; MRI=magnetic resonance imaging; PET=positron emission tomography.

SAFETY CONSIDERATIONS (cont'd) TREATMENT MONITORING

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.
- In Study 1, 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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How to initiate and monitor treatment with Kisunla

The prescribing clinician will be monitoring the patient throughout treatment for signs and symptoms of ARIA.

Initiating and Monitoring Treatment[4]

Infusions should be administered every 4 weeks. If an infusion is missed, resume administration every 4 weeks at the scheduled dose as soon as possible.[4]

If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated.[4]

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.[4] See Prescribing Information for additional dosing considerations.

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KISUNLA DOSING

PRE-INFUSION CHECKLIST

SELECT IMPORTANT SAFETY INFORMATION

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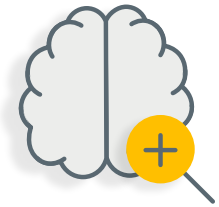
Prior to Each Infusion



CHECK >

INFORM >

DISCUSS >

TREATMENT MONITORING

HOW TO PREPARE FOR THE KISUNLA INFUSION

SELECT IMPORTANT SAFETY INFORMATION

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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 rarely can occur. 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.

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

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

kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Prior to Ea

CHECK

- ☐ Review the active infusion order form or medical record to confirm the dose and infusion number
- ☐ Confirm that the medical record contains complete and current clinical documentation prior to every treatment (hold the infusion and notify the prescriber if documentation is missing), including:
  - Presence of Aβ pathology prior to first infusion[4]
  - Recent baseline MRI prior to infusion 1 and prior to infusions 2, 3, 4, and 7[4]
- ☐ Consult with the prescriber prior to providing the infusion if:
  - Assessment is positive for signs/symptoms of ARIA, such as: headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur[4]
  - MRI has not been completed or shows radiographic evidence of ARIA[4]

Aß=amyloid beta; ARIA=amyloid-related imaging abnormalities; MRI=magnetic resonance imaging.

TREATMENT MONITORING

HOW TO PREPARE FOR THE KISUNLA INFUSION

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 rarely can occur. 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.

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Prior to Each Infusion

INFORM

- ☐ Inform patients about the risk of side effects, their signs and symptoms, and when to consult with their prescriber

CHECK > | INFORM > | DISCUSS >

TREATMENT MONITORING

HOW TO PREPARE FOR THE KISUNLA INFUSION

SELECT IMPORTANT SAFETY INFORMATION

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Prior to Each Infusion

DISCUSS

Discuss what to expect from the infusion process and next steps

Anticipate the possibility of providing support to patients with treatment reminders and/or transportation arrangements

Remind your patient that Lilly Support Services™ can provide assistance at **1-800-LillyRx (1-800-545-5979)**

TREATMENT MONITORING

HOW TO PREPARE FOR THE KISUNLA INFUSION

SELECT IMPORTANT SAFETY INFORMATION

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

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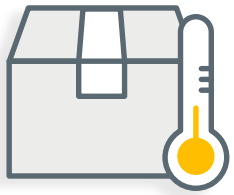
kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

How to Prepare for the Kisunla Infusion

ORDER KISUNLA

WHAT TO DO WHEN YOUR KISUNLA SHIPMENT ARRIVES



STORAGE

PREPARATION

ADMINISTRATION

Kisunla is supplied in one vial per carton as follows[4]:

350 mg/20 mL (17.5 mg/mL) single-dose vial: NDC 0002-9401-01.

PRE-INFUSION CHECKLIST

DOSING AND PREPARATION

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.
- 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.

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

How to Prepare for the Kisunla Infusion

ORDER KISUNLA

STORAGE

- ☐ When your Kisunla shipment arrives, make sure it is cold and there is no damage. Should you have concerns about your shipment, or if it doesn't arrive, please contact your specialty distributor.
  - — Store refrigerated at 2°C to 8°C (36°F to 46°F)
  - — Keep the vial in the outer carton to protect from light
  - — Do not freeze or shake
  - — If refrigeration is not available, may be stored at room temperature (20°C to 25°C [68°F to 77°F]) for up to 3 days

350 mg/20 mL (17.5 mg/mL) single-dose vial: NDC 0002-9401-01.

PRE-INFUSION CHECKLIST

DOSING AND PREPARATION

SELECT IMPORTANT SAFETY INFORMATION

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

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

PREPARATION

- ☐ Kisunla solution for infusion should be prepared and administered by a qualified healthcare professional using aseptic technique.[4]
- ☐ Gather all other supplies needed, including IV bags, tubing, different-sized bags, saline, and syringes.
- ☐ Allow Kisunla to warm to room temperature before preparation.[4]
- ☐ Inspect the content of the vial for particulate matter and discoloration prior to preparation. Kisunla solution is clear to opalescent, colorless to slightly yellow to slightly brown. Discard if discolored or foreign particles are observed.[4]
- ☐ Calculate the volume of Kisunla required to prepare the infusion solution. Each vial contains a Kisunla concentration of 350 mg/20 mL.[4] Use a new syringe for each vial. More than one vial is needed for a full dose[4]
  - — 700 mg of Kisunla: 40 mL
  - — 1400 mg of Kisunla: 80 mL
- ☐ Withdraw required volume of Kisunla and further dilute into an infusion bag containing 0.9% sodium chloride injection, to a final concentration of 4 mg/mL to 10 mg/mL. Each vial is for one-time use only. Discard any unused portion left in the vial.[4]
- ☐ Do not shake. Gently invert prepared infusion bag to mix. Visually inspect the Kisunla diluted solution for particles or discoloration prior to administration. Do not use if it is discolored, opaque, or foreign particles are seen. Use prepared dosing solution immediately.[4]

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.
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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

How to Prepare for the Kisunla Infusion

ADMINISTRATION

- ☐ Administer the diluted infusion solution via IV infusion over approximately 30 minutes.[4]
  - If not used immediately or if infusion is interrupted, store the dosing solution under refrigeration for up to 72 hours at 2°C to 8°C (36°F to 46°F) or for up to 12 hours at room temperature (20°C to 25°C [68°F to 77°F]), assuming dilution has taken place using aseptic techniques. Storage times include the duration of infusion
- ☐ If a serious infusion-related reaction or hypersensitivity occurs, stop the infusion immediately and treat per orders/protocol as clinically indicated.[4]
- ☐ Flush the line with 0.9% sodium chloride injection at the end of the infusion.[4]
- ☐ **Plan to observe the patient post-infusion for a minimum of 30 minutes to evaluate for any infusion-related or hypersensitivity reactions.[4]**

ORDER KISUNLA

PRE-INFUSION CHECKLIST

DOSING AND PREPARATION

SELECT IMPORTANT SAFETY INFORMATION

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

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(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

How to Prepare for the Kisunla Infusion

ORDER Kisunla

Kisunla is available through and can be shipped from an Authorized Specialty Distributor of Record. A full list of approved distributors can be found on trade.lilly.com.

Please contact your distributor directly for specific product availability and ordering.

Kisunla is supplied in one vial per carton as follows[4]:

350 mg/20 mL (17.5 mg/mL) single-dose vial: NDC 0002-9401-01.

PRE-INFUSION CHECKLIST

DOSING AND PREPARATION

SELECT IMPORTANT SAFETY INFORMATION

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

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Kisunla dosing and preparation[4]

Preparation and Reconstitution for Kisunla[4]

IV infusion Q4W	Kisunla dosage administered over ~30 minutes	Kisunla volume	Volume of 0.9% sodium chloride injection diluent	Final volume of diluted solution to be infused[a]
Infusions 1, 2, and 3	700 mg	40 mL	30 to 135 mL	70 to 175 mL
	2 vials of Kisunla needed			
Infusion 4+	1400 mg	80 mL	60 to 270 mL	140 to 350 mL
	4 vials of Kisunla needed			

[a]Final concentration of diluted solution is 4 mg/mL to 10 mg/mL.[4] IV=intravenous; Q4W=every 4 weeks.

ARIA=amyloid-related imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition.

HOW TO PREPARE FOR THE KISUNLA INFUSION

COVERAGE

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.
- There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data for dosing patients who experienced recurrent episodes of ARIA-E.

kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

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Coverage

Kisunla is covered for eligible Medicare patients if their provider enrolls them in a CMS-approved study that meets the requirements established by CMS

- CMS will provide coverage for FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease under Coverage with Evidence Development (CED) for patients who meet the following criteria:
  - Patient must be enrolled in Medicare
  - Patient must have a diagnosis of mild cognitive impairment due to AD or mild AD dementia, with documented evidence of beta-amyloid plaque on the brain
  - Physician must participate in a qualifying registry with an appropriate clinical team and follow-up care
- Lilly is committed to supporting patients, providers, and infusion centers in navigating the Medicare reimbursement landscape. To register your patient with CMS, submit here: https://qualitynet.cms.gov/alzheimers-ced-registry/submission

To learn more about registry requirements and billing and coding for Kisunla, please review the Billing and Coding Guide

CMS=Centers for Medicare & Medicaid Services

DOSING AND PREPARATION

LILLY SUPPORT SERVICES™ FOR KISUNLA

Lilly Support Services for Kisunla

Lilly Support Services for Kisunla helps patients get started on Kisunla and provides customized support along their treatment journey

- **Care Coordination:** This service on behalf of patients helps facilitate confirmation of requirements across their Kisunla treatment team, such as MRIs or other medical documentation to manage Kisunla treatment. Reminders will be provided to HCPs when additional documentation or tests are needed for patients on Kisunla. Lilly Support Services for Kisunla helps patients navigate the logistics associated with treatment to support a smoother experience while on Kisunla.
- **Lilly-Conducted Benefits Investigation:** Lilly Support Services for Kisunla provides assistance to research patient's insurance coverage to help identify the lowest out-of-pocket cost associated with the treatment of Kisunla. A copy of Summary of Benefits will be sent to the HCP's office, infusion center, and patient. Resources for Coverage Authorization and Appeals are also available. CMS registry enrollment information may be shared with the infusion center upon referral.
- **Infusion Center Locator:** Assistance is available to locate an infusion center that is preferable for patients to receive their Kisunla infusion. Register your site on the Kisunla locator tool at infusionlocator.kisunla.com/admin. Lilly Support Services for Kisunla can triage appropriate patient documentation to the chosen infusion center to ensure patients can get started on treatment as soon as possible.*
- **Nurse Navigator:** Customized support by a registered nurse will be available for patients throughout their treatment journey based on patients' needs. Nurse support helps patients understand what to expect with an infusion, answer questions about treatment and when to contact their HCP if needed, discuss next steps, and offer additional support as needed.

*The list of infusion centers provided in the locator is not comprehensive, and other infusion centers may be available to you and your patients. These lists are maintained by a third party and inclusion in the locator is not an endorsement of any of the centers.

MRI=magnetic resonance imaging; CMS=Center for Medicare & Medicaid Services

COVERAGE

PATIENT EXPERIENCE

SELECT IMPORTANT SAFETY INFORMATION

Infusion-Related Reactions (IRR)

IRRs were observed with Kisunla: 9% (74/853); placebo: 0.5% (4/874); the majority (70%, 52/74) occurred within the first 4 infusions. IRRs typically occur during infusion or within 30 minutes post-infusion. IRRs were mostly mild (57%) or moderate (39%) in severity. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, 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.

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

kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Understanding and Supporting Patients with Alzheimer's disease (AD)

- **Be supportive of the patient and their loved ones:** While patients with early symptomatic AD may still be independent, many may arrive to appointments with a loved one. Allowing the loved one to remain with the patient could help to relieve some of the anxieties associated with treatment and provide confidence for the patient. Consider the size of your infusion suite to accommodate loved ones and share your facility's policy on guests with patients. At the first appointment, establish a clear care partner who can help make decisions alongside the patient.[10]

- **Appointment reminders through both verbal and written communications:** Patients with early symptomatic Alzheimer's disease (AD) may have challenges with remembering appointments. Providing multiple appointment reminders through both verbal (ie, phone call) and written (ie, email or text) communications could help with appointment adherence.[10]

- **Outline the treatment process at each appointment:** Patients with early symptomatic AD may still have many cognitive faculties, but it could still be helpful to outline the treatment process at each appointment and answer questions they may have. These reminders and ongoing support throughout the infusion could go a long way in easing patient anxiety about the process.[10]

Lilly Support Services for Kisunla is available to help the patient along the treatment journey. If the patient is not already enrolled in Lilly Support Services for Kisunla, recommend they ask their HCP about how they can enroll to begin receiving personalized treatment support.

LILLY SUPPORT SERVICE FOR KISUNLA

ADDITIONAL SUPPORT

kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Additional Support

For product-related, infusion, or reimbursement questions, reach out to your Lilly Alzheimer's Disease Consultant or to Lilly Support Services for Kisunla.

For medical-related questions about Kisunla use or clinical data, speak with a trained medical professional.

Lilly Support Services:

1-800-LillyRx (1-800-545-5979)

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OTHER RESOURCES

Learn about Kisunla reimbursement and Medicare claims in the Billing and Coding Guide

Access the Kisunla infusion center locator tool: www.infusionlocator.kisunla.com.*

Register your practice as offering Kisunla at infusionlocator.kisunla.com/admin.

Download the Infusion Checklist here.

kisunla™ (donanemab-azbt) injection for IV infusion 350 mg/20 mL

Common Questions

Can patients with implants/pacemakers be treated with Kisunla?

What should I do if my patients experience ARIA?

What should I discuss with my patient before initiating treatment?

What should I do if I didn't receive the infusion shipment I was expecting?

How do I find information about insurance coverage and reimbursement requirements for Kisunla?

How long is the infusion duration? How long should the patient be monitored after infusion?

What infusion-related reactions (IRR) may occur?

What should I do if a hypersensitivity-related reaction or an infusion-related reaction occurs?

What do I do if my patient misses a dose?

ARIA=amyloid-related imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition; IV=intravenous; MRI=magnetic resonance imaging

ADDITIONAL SUPPORT
COMMON QUESTIONS (cont'd)

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

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Common Questions (cont'd)

Must Kisunla be administered via an IV pump? Is administering it to gravity an acceptable method?

If an infusion is interrupted, can I restart it? How long can the IV infusion bag be used after preparation, if administration is interrupted?

What should I do if my patient experiences an adverse reaction?

Were patients able to take symptomatic Alzheimer's disease (AD) medications in the clinical trial?

Were anticoagulants allowed in the placebo-controlled studies?

What assistance does Lilly Support Services for Kisunla offer?

How do I obtain Kisunla for my infusion site?

ARIA=amyloid-related imaging abnormalities; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition; IV=intravenous.

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WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

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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, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.

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

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

kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Common Questions

Can patients with implants/pacemakers be treated with Kisunla?

The ability to undergo an MRI is a requirement for treatment with Kisunla. In our trials, patients were excluded if they had any contraindications for MRI, including claustrophobia or the presence of contraindicated metal (ferromagnetic) implants/cardiac pacemakers.[5]

What should I do if my patients experience ARIA?

What should I discuss with my patient before initiating treatment?

What should I do if I didn't receive the infusion shipment I was expecting?

How do I find information about insurance coverage and reimbursement requirements for Kisunla?

How long is the infusion duration? How long should the patient be monitored after infusion?

What infusion-related reactions (IRR) may occur?

What should I do if a hypersensitivity-related reaction or an infusion-related reaction occurs?

What do I do if my patient misses a dose?

ADDITIONAL SUPPORT
COMMON QUESTIONS (cont'd)

Common Questions

Can patients with implants/pacemakers be treated with Kisunla?

What should I do if my patients experience ARIA?

- ARIA-E: Patients with mild MRI severity and with lack of symptoms of ARIA-E may continue dosing at current dose and schedule; if mild symptoms are present, patients may continue dosing based on clinical judgment. Patients with moderate or severe findings on MRI or moderate or severe symptoms of ARIA-E should suspend dosing until MRI shows radiographic resolution and symptoms resolve. Resuming dosing should be based on clinical judgement.[4]
- ARIA-H: Patients with mild MRI severity and with lack of symptoms of ARIA-H may continue dosing at current dose and schedule. Patients with moderate or severe findings on MRI or symptoms of ARIA-H should suspend dosing. Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. For any severe ARIA-H, use clinical judgment when considering whether to continue treatment or permanently discontinue.[4]

What should I discuss with my patient before initiating treatment?

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ADDITIONAL SUPPORT
COMMON QUESTIONS (cont'd)

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Common Questions

Can patients with implants/pacemakers be treated with Kisunla?

What should I do if my patients experience ARIA?

What should I discuss with my patient before initiating treatment?

- Discuss what your patient can expect from the infusion process, monitoring requirements, and next steps
- Advise patients to carry information that they are being treated with Kisunla
- Provide additional support as needed with appointment reminders or transportation arrangements
- Remind your patient that Lilly Support Services can provide assistance at **1-800-LillyRx (1-800-545-5979)**

What should I do if I didn't receive the infusion shipment I was expecting?

How do I find information about insurance coverage and reimbursement requirements for Kisunla?

How long is the infusion duration? How long should the patient be monitored after infusion?

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Common Questions

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What should I do if my patients experience ARIA?

What should I discuss with my patient before initiating treatment?

What should I do if I didn't receive the infusion shipment I was expecting?

Please contact your wholesaler directly.

How do I find information about insurance coverage and reimbursement requirements for Kisunla?

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What should I discuss with my patient before initiating treatment?

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How do I find information about insurance coverage and reimbursement requirements for Kisunla?

The most up-to-date coverage and reimbursement information can be found at kisunla.lilly.com/hcp/support-resources.

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Kisunla is administered via IV infusion over approximately 30 minutes. Patients should be monitored post-infusion for a minimum of 30 minutes to evaluate for infusion reactions and hypersensitivity reactions.[4]

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COMMON QUESTIONS (cont'd)

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Kisunla can cause IRR and hypersensitivity reactions including anaphylaxis and angioedema, some of which may be serious and life threatening. Signs and symptoms of infusion-related reactions include chills, erythema, nausea/vomiting, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure.[4]

What should I do if a hypersensitivity-related reaction or an infusion-related reaction occurs?

What do I do if my patient misses a dose?

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COMMON QUESTIONS (cont'd)

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What infusion-related reactions (IRR) may occur?

What should I do if a hypersensitivity-related reaction or an infusion-related reaction occurs?

Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction, and initiate appropriate therapy based on your center's protocol[4]

In the event of an infusion-related reaction, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Pretreatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing may be considered.[4]

ADDITIONAL SUPPORT
COMMON QUESTIONS (cont'd)

Common Questions

Can patients with implants/pacemakers be treated with Kisunla?

What should I do if my patients experience ARIA?

What should I discuss with my patient before initiating treatment?

What should I do if I didn't receive the infusion shipment I was expecting?

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What do I do if my patient misses a dose?

Infusions are to be administered every 4 weeks. If an infusion is missed, resume administration every 4 weeks at the same dose as soon as possible.[4]

ADDITIONAL SUPPORT
COMMON QUESTIONS (cont'd)

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kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Common Questions (cont'd)

Must Kisunla be administered via an IV pump? Is administering it to gravity an acceptable method?

Both methods are acceptable, as long as the infusion is administered over approximately 30 minutes.[4]

If an infusion is interrupted, can I restart it? How long can the IV infusion bag be used after preparation, if administration is interrupted?

What should I do if my patient experiences an adverse reaction?

Were patients able to take symptomatic Alzheimer's disease (AD) medications in the clinical trial?

Were anticoagulants allowed in the placebo-controlled studies?

What assistance does Lilly Support Services for Kisunla offer?

How do I obtain Kisunla for my infusion site?

COMMON QUESTIONS

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Common Questions (cont'd)

Must Kisunla be administered via an IV pump? Is administering it to gravity an acceptable method?

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After dilution, immediate use is recommended. If the Kisunla diluted solution is not used immediately after preparation, it can be stored under refrigeration for up to 72 hours at 2°C to 8°C (36°F to 46°F) or for up to 12 hours at room temperature: 20°C to 25°C (68°F to 77°F). Do not freeze the Kisunla diluted solution.[4]

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What should I do if my patient experiences an adverse reaction?

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Were patients able to take symptomatic Alzheimer's disease (AD) medications in the clinical trial?

Approved standard-of-care symptomatic treatments for AD, such as donepezil and memantine, were permitted in the trial, provided that dosage of such medications was stable within 2 months of starting treatment with Kisunla. No dose modifications of these medications were required.[4,5]

Were anticoagulants allowed in the placebo-controlled studies?

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Were patients able to take symptomatic Alzheimer's disease (AD) medications in the clinical trial?

Were anticoagulants allowed in the placebo-controlled studies?

Yes, these medications were not excluded. However, given that ARIA-H and intracerebral hemorrhages >1 cm in diameter have been observed in patients taking Kisunla, additional caution should be exercised when considering administration of antithrombotic or thrombolytic agents to a patient already being treated with Kisunla. 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 intracerebral hemorrhage in patients taking antithrombotic 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.[4,5]

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IMPORTANT SAFETY INFORMATION

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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 rarely can occur. 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, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.

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

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

kisunla™
(donanemab-azbt)
injection for IV infusion
350 mg/20 mL

Common Questions (cont'd)

Must Kisunla be administered via an IV pump? Is administering it to gravity an acceptable method?

If an infusion is interrupted, can I restart it? How long can the IV infusion bag be used after preparation, if administration is interrupted?

What should I do if my patient experiences an adverse reaction?

Were patients able to take symptomatic Alzheimer's disease (AD) medications in the clinical trial?

Were anticoagulants allowed in the placebo-controlled studies?

What assistance does Lilly Support Services for Kisunla offer?

Lilly Support Services for Kisunla can answer questions, provide appointment reminders, complete a benefits investigation, locate infusion centers, provide education on side effects of Kisunla, and support patients and providers in reimbursement processes.

How do I obtain Kisunla for my infusion site?

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Kisunla can be shipped from an Authorized Specialty Distributor of Record. Please contact your distributor directly for specific product availability.

COMMON QUESTIONS

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IMPORTANT SAFETY INFORMATION FOR KISUNLA™ (DONANEMAB-AZBT)

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ApoE ε4 Homozygotes: Patients who are apolipoprotein E ε4 (ApoE ε4) 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 ε4 status should be performed prior to initiation of treatment 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. 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 ε4 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 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)

Kisunla can cause ARIA-E, which can be observed on magnetic resonance imaging (MRI) as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. 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 generally occurs with ARIA-E.

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. 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 addition to ARIA, intracerebral hemorrhages (ICH) >1 cm in diameter have occurred in patients treated with Kisunla.

Incidence of ARIA

Symptomatic ARIA occurred in 6% (52/853) of patients treated with Kisunla. Clinical symptoms associated with ARIA resolved in approximately 85% (44/52) of patients.

Including asymptomatic radiographic events, ARIA was observed with Kisunla: 36% (307/853); placebo: 14% (122/874). ARIA-E was observed with Kisunla: 24% (201/853); placebo: 2% (17/874). ARIA-H was observed with Kisunla: 31% (263/853); placebo: 13% (111/874). There was no increase in isolated ARIA-H for Kisunla vs placebo.

Incidence of ICH

ICH >1 cm in diameter was reported in 0.5% (4/853) of patients after treatment with Kisunla vs 0.2% (2/874) on placebo. Fatal events of ICH have been observed.

Risk Factors for ARIA and ICH

ApoE ε4 Carrier Status

The risk of ARIA, including symptomatic and serious ARIA, is increased in apolipoprotein E ε4 (ApoE ε4) homozygotes. 17% (143/850) of patients in the Kisunla arm were ApoE ε4 homozygotes, 53% (452/850) were heterozygotes, and 30% (255/850) were noncarriers. The incidence of ARIA was higher in ApoE ε4 homozygotes (Kisunla: 55%; placebo: 22%) than in heterozygotes (Kisunla: 36%; placebo: 13%) and noncarriers (Kisunla: 25%; placebo: 12%). Among patients treated with Kisunla, symptomatic ARIA-E occurred in 8% of ApoE ε4 homozygotes compared with 7% of heterozygotes and 4% of noncarriers. Serious events of ARIA occurred in 3% of ApoE ε4 homozygotes, 2% of heterozygotes, and 1% of noncarriers.

The recommendations for management of ARIA do not differ between ApoE ε4 carriers and noncarriers. 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.

Important Safety Information continued on next page

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IMPORTANT SAFETY INFORMATION FOR KISUNLA™ (CONT'D)

Radiographic Findings of Cerebral Amyloid Angiopathy (CAA) (cont'd)

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 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 incidence of ARIA-H was 30% (106/349) in patients taking Kisunla with a concomitant antithrombotic medication within 30 days vs 29% (148/504) in patients who did not receive an antithrombotic within 30 days of an ARIA-H event. The incidence of ICH >1 cm in diameter was 0.6% (2/349) in patients taking Kisunla with a concomitant antithrombotic medication vs 0.4% (2/504) in those who did not receive an antithrombotic. 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. 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.

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. 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.

Radiographic Severity

The majority of ARIA-E radiographic events occurred early in treatment (within the first 24 weeks), although ARIA can occur at any time and patients can have more than one episode. The maximum radiographic severity of ARIA-E in patients treated with Kisunla was mild in 7% (59/853), moderate in 15% (128/853), and severe in 2% (14/853). Resolution on MRI after the first ARIA-E event occurred in 63% of patients treated with Kisunla by 12 weeks, 80% by 20 weeks, and 83% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in patients treated with Kisunla was mild in 17% (143/853), moderate in 4% (34/853), and severe in 5% (40/853). The maximum radiographic severity of ARIA-H superficial siderosis in patients treated with Kisunla was mild in 6% (47/853), moderate in 4% (32/853), and severe in 5% (46/853). Among patients treated with Kisunla, the rate of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes 3% (4/143) vs heterozygotes 2% (9/452) or noncarriers 0.4% (1/255). The rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes 22% (31/143) vs heterozygotes 8% (38/452) or noncarriers 4% (9/255).

Monitoring and Dose Management Guidelines

Baseline brain MRI and periodic monitoring with MRI are recommended. 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.

There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data for dosing patients who experienced recurrent episodes of ARIA-E.

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: 9% (74/853); placebo: 0.5% (4/874); the majority (70%, 52/74) occurred within the first 4 infusions. IRRs typically occur during infusion or within 30 minutes post-infusion. IRRs were mostly mild (57%) or moderate (39%) in severity. IRRs resulted in discontinuations in 4% (31/853). Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, 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. Pretreatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing may be considered.

Adverse Reactions: The most common adverse reactions reported in ≥5% of patients treated with Kisunla (n=853) and ≥2% higher than placebo (n=874): ARIA-H microhemorrhage (25% vs 11%), ARIA-E (24% vs 2%), ARIA-H superficial siderosis (15% vs 3%), headache (13% vs 10%), IRRs (9% vs 0.5%).

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References: 1. Porsteinsson AP, Isaacson RS, Knox S, et al. Diagnosis of early Alzheimer's disease: clinical practice in 2021. *J Prev Alzheimers Dis*. 2021;8:371-386. **2.** Jack CR Jr, Knopman DS, Jagust WJ, et al. Tracking pathophysiological processes in Alzheimer's disease: an updated hypothetical model of dynamic biomarkers. *Lancet Neurol*. 2013;12(2):207-216. **3.** Alzheimer's Association. 2022 Alzheimer's disease facts and figures. *Alzheimers Dement*. 2022;18(4):700-789. **4.** Kisunla (donanemab-azbt). Prescribing Information. Lilly USA, LLC. **5.** Sims JR, Zimmer JA, Evans CD, et al; for TRAILBLAZER-ALZ 2 Investigators. Donanemab in early symptomatic Alzheimer disease: the TRAILBLAZER-ALZ 2 randomized clinical trial. *JAMA*. 2023;330(6):512-527. **6.** 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. **7.** Data on File. Lilly USA, LLC. DOF-DN-US-0053. **8.** Data on File. Lilly USA, LLC. DOF-DN-US-0049. **9.** Barakos J, Purcell D, Suhy J, et al. Detection and management of amyloid-related imaging abnormalities in patients with Alzheimer's disease treated with anti-amyloid beta therapy. *J Prev Alzheimers Dis*. 2022;9(2):211-220. **10.** Tarawneh R, Holtzman DM. The clinical problem of symptomatic Alzheimer disease and mild cognitive impairment. *Cold Spring Harb Perspect Med*. 2012;2(5):a006148.

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