kisunla™
(donanemab-azbt)
injection for
intravenous use

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Actor portrayal. Kisunla is not indicated for children.

AN OVERVIEW OF TREATING WITH KISUNLA

WITH GRADUAL TITRATION: SEE INSIDE FOR DOSING AND SAFETY DATA

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

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STARTING TREATMENT

Infusion

- Provide a complete infusion referral with documentation supporting treatment initiation, including:
  - Medical records confirming cognitive impairment using a validated tool, such as MMSE, MoCA, or other assessment
  - Type of test, results, and date of diagnostic testing confirming Aß pathology
  - A recent brain MRI prior to initiating treatment to monitor for pre-existing ARIA[1]
  - Confirmation of patient enrollment in coverage with evidence development registry, if insured by Medicare
- Kisunla is an IV infusion administered over approximately **30 minutes once every 4 weeks**[1]
- Patients should be observed for a minimum of **30 minutes post-infusion** to monitor for IRRs and hypersensitivity[1]

Monitoring

- After baseline brain MRI, **conduct a brain MRI** before infusions 2, 3, 4, and 7 and if symptoms consistent with ARIA occur[1]

Dosing Considerations

- Consider stopping dosing based on removal of amyloid plaques to minimal levels consistent with a visually negative amyloid PET scan[1]

In Phase 3 clinical trials, dosing was stopped based on 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.[1]

In clinical trials, 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.[1]

For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[5]

TRAILBLAZER-ALZ 2 trial design

The safety and efficacy of Kisunla were evaluated in a Phase 3, randomized, double-blind, placebo-controlled study that assessed disease progression in early symptomatic Alzheimer's disease (AD) (including those with MCI or mild dementia) by reducing amyloid plaques. The study was powered to test the results of Kisunla in the low-medium tau population[§] (N=1182) and allowed enrollment of high tau participants so Kisunla could also be tested in the overall population (the low-medium tau population plus high tau participants) (N=1736). Participants were included in the study if they had confirmed presence of amyloid pathology. 1736 patients were randomized 1:1 to receive 700 mg of Kisunla every 4 weeks for the first 3 infusions, and then 1400 mg every 4 weeks (n=860) or placebo (n=876) for a total of up to 72 weeks. The primary efficacy endpoint was change in the iADRS score from baseline to 76 weeks (impact on cognitive and functional decline). Patients were treated until amyloid plaque levels reached a minimal level[‖] (assessed with amyloid PET scans at 24, 52, and 76 weeks), or until discontinuation, or study completion (76 weeks). ARIA-monitoring MRI at baseline and before 4, 12, 24, 52, and 76 weeks and unscheduled MRIs at investigator discretion.[1,5,¶]

[§]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).[1]

[‖]In the study, 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.[1]

[¶]The full Prescribing Information recommends ARIA- monitoring MRI before infusions 1, 2, 3, 4, and 7.[1]

For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[5]

Aß=amyloid-ß; iADRS=integrated Alzheimer's Disease Rating Scale; IRR=infusion-related reaction; IV=intravenous; MoCA=Montreal Cognitive Assessment; MRI=magnetic resonance imaging; PET=positron emission tomography; ARIA=amyloid-related imaging abnormalities; MMSE=Mini-Mental State Examination. iADRS=integrated Alzheimer's Disease Rating Scale; SUVR=standardized uptake value ratio.

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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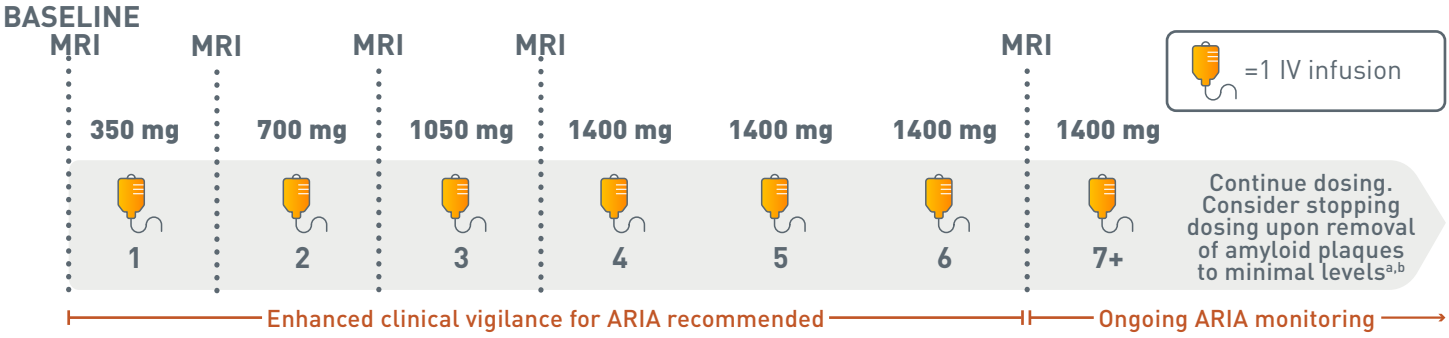
ONCE-MONTHLY KISUNLA IS THE FIRST AND ONLY FDA-APPROVED AMYLOID-TARGETING THERAPY (ATT) WITH DOSING INSTRUCTIONS THAT ALLOW FOR LIMITED-DURATION TREATMENT[1]*

Administer Kisunla every 4 weeks as an IV infusion over approximately 30 minutes at the following dosing schedule: 350 mg for the first dose, 700 mg for the second dose, 1050 mg for the third dose, followed by 1400 mg every 4 weeks[1]

Observe the patient post-infusion for a minimum of 30 minutes, and consider longer periods of observation if clinically indicated, to evaluate for infusion reactions and hypersensitivity reactions. The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider pre- medication at subsequent dosing with antihistamines, NSAIDs, or corticosteroids.[1]

If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated.[1]

How to Initiate and Monitor Treatment With Kisunla[1]



ARIA=amyloid-related imaging abnormalities; IV=intravenous; MRI=magnetic resonance imaging

*In Phase 3 clinical trials, 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.[1]

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

[a] In clinical trials, completion of active treatment was based on amyloid PET levels measured at week 24, week 52, and week 76. If the amyloid plaque level was <11 Centiloids on a single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, participants taking Kisunla were eligible to switch to placebo.[1]

[b] For reference, <24.1 Centiloids on an amyloid PET scan is consistent with a negative visual read.[5]

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.

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GRADUAL-TITRATION DOSING[1]

For your patients with early symptomatic Alzheimer's disease (AD) and confirmed amyloid positivity[1]

In TRAILBLAZER-ALZ 6, alternative dosing regimens with Kisunla were assessed. The primary endpoint was the proportion of participants with any occurrence of **ARIA-E.**[1]

Assessed the impact of gradual-titration dosing* on ARIA-E frequency and amyloid plaque reduction[1]

- Participants (N=842) were randomized to 1 of 4 alternative Kisunla dosing regimens in a 1:1:1:1 ratio,† including:
- **Original dosing (N=207)‡:** Consistent with TRAILBLAZER-ALZ 2
- **Gradual-titration dosing (N=212):** 350 mg for the first dose, 700 mg for the second dose, and 1050 mg for the third dose, followed by 1400 mg every 4 weeks (Q4W)

Inclusion and exclusion criteria were the same as TRAILBLAZER-ALZ 2 except that tau PET was not an inclusion criterion.[1]

*The treatment period was up to 72 weeks; treatment stopping criteria based on amyloid PET were the same as TRAILBLAZER-ALZ 2.[1]

†1:1:1:1 randomization stratified by ApoE ε4 carrier status and by baseline amyloid PET. For the original and gradual-titration dosing arms, placebo was given every other week for the first 16 weeks to preserve blinding for additional arms (not shown) to explore pharmacokinetics.[6]

‡Original dosing was 700 mg for the first, second, and third dose (700/700/700 mg), followed by 1400 mg Q4W.[1]

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.
- 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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THE SAFETY OF KISUNLA WAS STUDIED IN MORE THAN 3700 PARTICIPANTS[1§]

Adverse reactions reported in 2 Kisunla Phase 3 clinical trials[1,6]

TRAILBLAZER-ALZ 2 Adverse Reactions Reported in ≥5% of Patients Treated With Kisunla and ≥2% Higher Than Placebo at 76 Weeks[1]

	ARIA-E	ARIA-H	Microhemorrhage	Superficial siderosis	Headache	Infusion-related reaction (IRR)
Original Dosing[a] Kisunla (n=853)	24%	31%	25%	15%	13%	9%
Placebo (n=874)	2%	13%	11%	3%	10%	0.5%

In TRAILBLAZER-ALZ 2, ARIA[b] (including asymptomatic radiographic events) was observed in 36% of participants treated with Kisunla compared with 14% of participants treated with placebo.[1] **Symptomatic ARIA-E was observed in 6% of patients treated with Kisunla compared to 0% of patients treated with placebo.** Clinical symptoms associated with ARIA- E resolved in approximately 85% of patients taking Kisunla.[1,7]

[a] Original dosing was 700 mg for the first, second, and third dose (700/700/700 mg), followed by 1400 mg every 4 weeks (Q4W). This is the previously approved dosing regimen.[1] Please refer to the package insert for dosing instructions.

[b]ARIA-E includes brain edema or sulcal effusions. ARIA-H most commonly includes microhemorrhage and superficial siderosis.[1]

TRAILBLAZER-ALZ 6 at 52 Weeks[1,6]

	ARIA-E	ARIA-H	Microhemorrhage	Superficial siderosis	Headache	Infusion-related reaction (IRR)[a]
Original Dosing Kisunla (n=207)	**25%**	28%	21%	15%	21%	14%
Gradual-Titration Dosing[b] Kisunla (n=212)	**16%**	25%	23%	8%	18%	16%

In TRAILBLAZER-ALZ 6, ARIA (including asymptomatic radiographic events) was observed in 34% of participants treated with the original dosing regimen compared with 29% of participants treated with gradual-titration dosing.[20] The primary endpoint of TRAILBLAZER-ALZ 6 was the proportion of participants with any occurrence of ARIA-E.[1] **Symptomatic ARIA-E was observed in 5% of patients in the original dosing arm compared to 3% of patients in the gradual-titration arm.** Clinical symptoms associated with ARIA-E resolved in approximately 90% of patients in the original dosing arm compared to 67% of patients in the gradual-titration arm.[21]

[a]In TRAILBLAZER-ALZ 6, placebo was given every other visit to preserve blinding for additional arms (not shown) to explore pharmacokinetics.[6]

[b]Gradual-titration dosing was 350 mg for the first dose, 700 mg for the second dose, and 1050 mg for the third dose, followed by 1400 mg Q4W).[1]

In TRAILBLAZER-ALZ 6, gradual-titration dosing reduced the frequency of ARIA-E compared to the original dosing[1]

Clinical trials are conducted under varying conditions, so rates of adverse reactions observed in one trial cannot be directly compared to another and may not reflect what is observed in practice.

[§]The safety of Kisunla has been evaluated in 3727 patients with Alzheimer's disease (AD) who received at least 1 dose of Kisunla intravenously across 2 Phase 3 clinical trials.[1]

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

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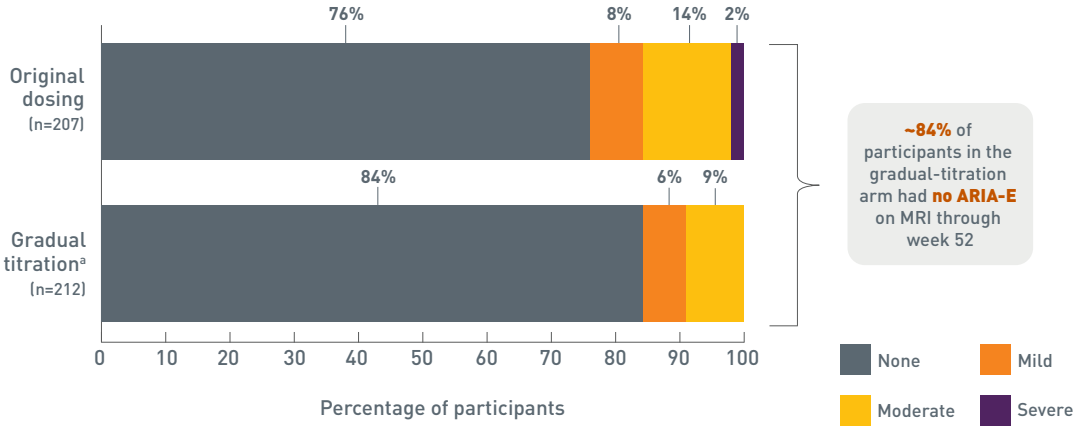
REDUCED ARIA-E RADIOGRAPHIC SEVERITY WAS SEEN IN THE GRADUAL-TITRATION* ARM COMPARED TO THE ORIGINAL-DOSING† ARM IN TRAILBLAZER-ALZ 6[1]

ARIA-E Severity Distribution Shifted Toward None or Less Severe in the Gradual-Titration Arm[1,6]



In TRAILBLAZER-ALZ 2 at 76 weeks[19]:

- Maximum radiographic severity of ARIA-E in patients taking Kisunla; mild: 7% (59/853); moderate: 15% (128/853); and severe: 2% (14/853). Maximum radiographic severity of ARIA-E in patients on placebo: mild: 2% (14/874); moderate: 0.3% (3/874); and severe: 0% (0/874)
- Maximum radiographic severity of ARIA-H microhemorrhage and ARIA-H superficial siderosis for patients taking Kisunla, respectively: mild: 17% (143/853) and 6% (47/853); moderate: 4% (34/853) and 4% (32/853); and severe: 5% (40/853) and 5% (46/853). Maximum radiographic severity of ARIA-H microhemorrhage and ARIA-H superficial siderosis for patients on placebo, respectively: mild: 10% (88/874) and 2% (16/874); moderate: 1% (11/874) and 1% (5/874); and severe: 0.1% (1/874) and 0.2% (2/874)

In patients taking Kisunla in TRAILBLAZER-ALZ 6 at 52 weeks[19]:

- Maximum radiographic severity of ARIA-H microhemorrhage and ARIA-H superficial siderosis in patients in the gradual-titration arm were, respectively: mild: 18% (37/212) and 4% (9/212); moderate: 3% (6/212) and 3% (6/212); and severe: 2% (5/212) and 1% (3/212)
- Maximum radiographic severity of ARIA-H microhemorrhage and ARIA-H superficial siderosis in patients in the original dosing arm were, respectively: mild: 14% (28/207) and 9% (18/207); moderate: 5% (10/207) and 2% (4/207); and severe: 3% (6/207) and 4% (9/207)

[a]Due to rounding, numbers presented may not add up to the totals indicated, and percentages may not reflect the absolute figures for the same reason.

*Gradual-titration dosing was 350 mg for the first dose, 700 mg for the second dose, and 1050 mg for the third dose, followed by 1400 mg every 4 weeks (Q4W).[1]

†Original dosing was 700 mg for the first, second, and third dose (700/700/700 mg), followed by 1400 mg Q4W. This is the previously approved dosing regimen.[1] Please refer to the package insert for dosing instructions.

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 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.

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CLASSIFICATION OF THE RADIOGRAPHIC SEVERITY OF ARIA[1]

ARIA MRI CLASSIFICATION CRITERIA[1]

ARIA Type	Radiographic Severity		
	Mild	Moderate	Severe
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortex white matter in one location <5 cm	FLAIR hyperintensity 5 to 10 cm in single greatest dimension, or more than 1 site of involvement, each measuring <10 cm	FLAIR hyperintensity >10 cm with associated gyral swelling and sulcal effacement. One or more separate/independent sites of involvement may be noted
ARIA-H microhemorrhage	Less than or equal to 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 new[a] focal area of superficial siderosis	2 new focal areas of superficial siderosis	Greater than 2 new focal areas of superficial siderosis

[a]Includes new or worsening superficial siderosis[1]

ARIA=amyloid-related imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema; ARIA-H=amyloid-related imaging abnormalities-hemosiderin deposition; FLAIR=fluid-attenuated inversion recovery; MRI=magnetic resonance imaging.

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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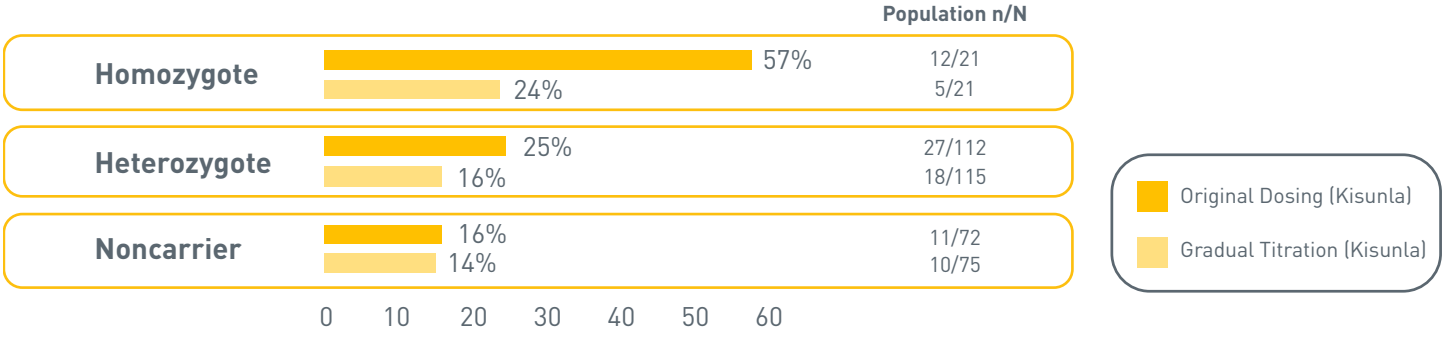
RATES OF ARIA-E ACROSS ApoE ε4 GENOTYPES

TRAILBLAZER-ALZ 6 at 52 Weeks[1]

Percentage of participants with ARIA-E through 52 weeks



The small number of events and limited exposure in the ApoE ε4 subgroups limit definitive conclusions about the risk of ARIA-E.

In TRAILBLAZER-ALZ 6, ApoE ε4 homozygotes saw reduced rates of ARIA-E from 57% (original dosing) to 24% (gradual-titration dosing)[1]

In TRAILBLAZER-ALZ 2, of patients in the Kisunla arm (n=850), 17% (n=143) were ApoE ε4 homozygotes, 53% were heterozygotes (n=452), and 30% (n=255) were noncarriers. The incidence of ARIA through 76 weeks was higher in ApoE ε4 homozygotes (55% on Kisunla vs 22% on placebo) than in heterozygotes (36% on Kisunla vs 13% on placebo) and noncarriers (25% on Kisunla vs 12% on placebo).[1]

ApoE ε4=apolipoprotein E type 4 allele; ARIA=amyloidrelated imaging abnormalities; ARIA-E=amyloid-related imaging abnormalities-edema.

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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, 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.

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AVAILABLE ApoE ε4 BLOOD TESTS[10-15,a]

Company	Test Name	Contact Information	Order test
Genotype tests ApoE **genotype** tests can distinguish an individual's alleles—ε2, ε3, or ε4—and if they are homozygous, heterozygous, or non-carriers			
Labcorp	APOE	(336) 436-7089 cgservices@labcorp.com	Order test
Athena Diagnostics®	ADmark® ApoE Genotype Analysis and Interpretation (Symptomatic)	(800) 394-4493 genetics@athenadiagnostics.com	Order test
Mayo Clinical Labs	APOE Genotyping	(800) 533-1710 mcl@mayo.edu	Order test
Proteotype tests The APOE gene produces the ApoE4 protein, and some laboratory tests determine ApoE status by assessing the patient's **proteotype**. Please confirm with the testing lab or manufacturer the test capabilities to distinguish between homozygous, heterozygous, and noncarriers			
Quest Diagnostics®	Quest AD-Detect® Apolipoprotein E (ApoE) Isoform	(866) 697-8378	Order test
C_2N Diagnostics	Precivity-ApoE™	(877) 226-3424 info@c2n.com	Order test
C_2N Diagnostics	Precivity-AD™	(877) 226-3424 info@c2n.com	Order test
Randox Laboratories Ltd.	ApoE4	(866) 472-6369	Order test

There is currently no available FDA-approved test for detection of ApoE ε4 alleles to identify patients at risk of ARIA if treated with Kisunla. Currently available tests used to identify ApoE ε4 alleles may vary in accuracy and design.

[a]Certain tests can provide information about the combination of ApoE alleles (eg, differentiate ApoE ε4 heterozygotes vs homozygotes). Please see the intended use for the test, or contact the laboratory to ensure your test can detect ApoE alleles.

This list is intended for informational purposes and your consideration only, and is based on publicly available information as of April 30, 2024, for these organizations. Eli Lilly and Company (Lilly) makes no representations regarding the clinical or analytical validity, manufacturing quality, or design of the testing offered by the vendors included on this list. Inclusion on this list does not represent an endorsement, referral, or recommendation by Lilly. Contact the vendor for more information.

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ARIA MANAGEMENT

DOSING RECOMMENDATIONS FOR PATIENTS WITH ARIA-E[1]

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

[a] Mild: discomfort noticed, but no disruption of normal daily activity; Moderate: discomfort sufficient to reduce or affect normal daily activity; Severe: incapacitating, with inability to work or to perform normal daily activity.[1]

[b]Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.[1]

DOSING RECOMMENDATIONS FOR PATIENTS WITH ARIA-H[1]

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

[a]Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.[1]

[b]Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgment when considering whether to continue treatment or permanently discontinue Kisunla.[1]

In patients who develop intracerebral hemorrhage >1 cm in diameter during treatment with Kisunla, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgment when considering whether to continue treatment or permanently discontinue Kisunla after radiographic stabilization and resolution of symptoms.[1]

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

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.

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COMMON QUESTIONS

Were patients able to take symptomatic 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.[1,4]

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.[1,5]

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.[1]
- 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.[1]

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.[4]

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™ for Kisunla can provide assistance at **1-800-LillyRx (1-800-545-5979)**

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

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

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ALL MEDICARE PLANS AND CONTRACTORS COVER AMYLOID-TARGETING THERAPIES (ATTS), INCLUDING KISUNLA, UNDER COVERAGE WITH EVIDENCE DEVELOPMENT (CED)[16,17,1]

National Coverage Determination (NCD) on monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) (200.3)[16,17]

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 documented evidence of beta-amyloid plaques in the brain
- Physician must participate in a qualifying registry* with an appropriate clinical team and follow-up care†

*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).[4]

MCI=mild cognitive impairment.

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

LILLY SUPPORT SERVICES™ FOR KISUNLA GETS YOUR PATIENTS STARTED AND HELPS KEEP THEM ON TRACK WITH KISUNLA

CUSTOMIZED SUPPORT AND RESOURCES FOR YOUR PATIENTS

CARE COORDINATION

To help patients navigate treatment, this optional service on behalf of your patients helps coordinate reimbursement and adherence requirements (such as MRIs or other medical documentation) across a patient's Kisunla treatment team. Lilly Support Services will request that the HCP routinely submit information via the Care Coordination Form. Care Coordination also includes outreach to the site of care (HCP office or infusion center) to collect infusion appointment dates. Patients enrolled in this service may receive appointment reminders for infusions.

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 may be sent to the HCP's office, infusion center, and patient. Resources for Coverage Authorization and Appeals are also available.

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.*

APPOINTMENT REMINDERS

Remembering multiple sites of care and staying on top of appointments could be difficult for patients, but Lilly Support Services for Kisunla is here to help. For patients enrolled in Care Coordination, appointment reminders for infusions may be provided to help keep patients on track.

NURSE NAVIGATOR

Customized support by a registered nurse is available for patients throughout their treatment journey based on patients' needs. Nurse support helps patients understand what to expect with an infusion and answers questions about treatment and when to contact their HCP if needed, discusses next steps, and offers additional support as needed.

FIELD REIMBURSEMENT MANAGER (FRM) SUPPORT

FRMs are experienced access professionals committed to helping navigate the complex access and reimbursement environment to help patients get access to Kisunla. FRMs are integrated with support programs, understand support program resources, access challenges, affordability options, and the infusion center network.

*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.

†A Customer Care Coordinator provided by Lilly Support Services is not a medical professional.

To start your patient, complete the Lilly Support Services for Kisunla Enrollment Form or call 1-800-LillyRx (1-800-545-5979) if you have questions.

Completing and submitting the Lilly Support Services for Kisunla Enrollment Form enables you to enroll the patient in the Kisunla support program; the prescription and infusion order may be sent to the preferred infusion center, if requested.

Search for an infusion center for your patient.

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

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

GET STARTED WITH KISUNLA

- ☐ Enroll your patient in Lilly Support Services™ for Kisunla by downloading the Enrollment Form at **kisunla.lilly.com/assets/pdf/kisunlaenrollmentform.pdf** or complete digital enrollment via the Digital Enrollment Portal at **enroll.LillySupportServices.Lilly.com**. You and your patient will need to complete and sign the Enrollment Form. Fax completed Enrollment Forms to **1-844-731-2697.** For questions, call **1-800-LillyRx (1-800-545-5979)**
- ☐ Find an infusion center preferable to your patient with our locator tool at **www.infusionlocator.kisunla.com**, or let Lilly Support Services for Kisunla help by requesting infusion center locator support on the Enrollment Form
- ☐ Plan for and promptly schedule monitoring MRIs in advance
- ☐ To find an imaging center, contact your Lilly Alzheimer's Disease Consultant or call **1-800-LillyRx (1-800-545-5979)**
- ☐ Provide your patient with the Getting Started resource

MRI=magnetic resonance imaging

ADDITIONAL SUPPORT FROM YOUR LILLY TEAM

For product-related, infusion, or reimbursement questions, reach out to your Lilly Alzheimer's Disease Consultant or to Lilly Support Services for Kisunla at **1-800-LillyRx (1-800-545-5979)**.

For medical-related questions about Kisunla use or clinical data, speak with a trained medical professional by calling: **1-800-LillyRx (1-800-545-5979)**.

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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.

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.

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) (con'd)

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

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.

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 see full Prescribing Information for Kisunla, including Boxed Warning regarding ARIA, and Medication Guide.

DN HCP ISI 01JUL2025

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