From diagnosis to infusion

YOUR ROAD MAP FOR LEQEMBI®

Miyoko is an actual patient with AD. Patient not on LEQEMBI.

This document will inform you of the steps required for diagnosis to infusion in order to initiate LEQEMBI in appropriate patients.

AD=Alzheimer's disease.

LEQEMBI®
(lecanemab-irmb) 100 mg/mL
INJECTION FOR INTRAVENOUS USE

INDICATION

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

SELECT SAFETY INFORMATION: Boxed WARNING

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES (ARIA)

- **Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause ARIA, characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur. ARIA can be fatal. Serious intracerebral hemorrhages (ICH) >1 cm, some of which have been fatal, have been observed with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy to a patient being treated with LEQEMBI.**
  - **Apolipoprotein E ε4 (ApoE ε4) Homozygotes: Patients who are ApoE ε4 homozygotes (~15% of patients with AD) treated with this class of medications 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 LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.**
- **Consider the benefit of LEQEMBI for the treatment of AD and the potential risk of serious ARIA events when deciding to initiate treatment with LEQEMBI.**

Please see additional Select Safety information throughout and click here for full Prescribing Information for LEQEMBI, including Boxed WARNING.

Overview of steps from diagnosis to treatment with LEQEMBI®

1 Check for cognitive impairment

2 Rule out non-AD causes

3 Confirm AD diagnosis*

Diagnose and prepare[1-3]

*Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with LEQEMBI.

AD=Alzheimer's disease; ApoE ε4=apolipoprotein E ε4; ARIA=amyloid-related imaging abnormality.

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4 **Conduct baseline MRI to evaluate for pre-existing ARIA and begin initiation of dosing regimen**

5 **Perform follow-up MRIs to monitor for ARIA**

6 **Consider transitioning to maintenance dosing regimen after 18 months†**

Initiate treatment and monitor for safety and infusion reactions.

†After 18 months, patients may continue with twice-monthly dosing (once every 2 weeks), or a transition to once-monthly dosing (once every 4 weeks) may be considered.

ARIA=amyloid-related imaging abnormality; MRI=magnetic resonance imaging.

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Diagnose and prepare for LEQEMBI®

Step 1: Check for cognitive impairment: clinical evaluation for MCI due to AD and mild AD dementia

LEQEMBI is indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.[1]

To assess for these diagnoses, conduct the following tests:

Use MCI due to AD-sensitive and/or mild AD dementia-sensitive cognitive assessments

- When cognitive changes in a patient are first suspected, cognitive assessment is necessary using diagnostic tools calibrated to detect early AD[4,5]
- Use an MCI due to AD-sensitive and/or mild AD dementia-sensitive tool such as MoCA, Qmci screen, MMSE, Mini-Cog, SLUMS, and AD8[2,3,6,7]
- Notes _____

Step 2: Rule out non-AD causes, differential diagnosis

- As a part of diagnosis, structural imaging tests should be conducted to rule out other causes of MCI not related to AD, such as tumors, evidence of small or large strokes, damage from severe head trauma, or a buildup of fluid in the brain[2,8]
- Test used (eg, CT scan, MRI)[2,8]
- Lab work should be conducted to rule out other conditions that may cause cognitive dysfunction such as vitamin B12 deficiency and thyroid diseases[9]
- Notes _____

Step 3: Confirm AD diagnosis with presence of Aβ pathology

- Biomarker-confirmed AD diagnosis allows for the identification of patients appropriate for Aβ-targeting therapy[10]
- Options for performing Aβ confirmation include amyloid PET scans, CSF assays, BBBM assays*[10,11]
- Notes _____

*BBBM analysis is currently under investigation as a newer alternative to PET imaging and CSF-based testing methods for AD.[10-12]

Aβ=amyloid beta; AD=Alzheimer's disease; AD8=Eight-item Informant Interview to Differentiate Aging and Dementia; BBBM=blood-based biomarker; CSF=cerebrospinal fluid; CT=computed tomography; MCI=mild cognitive impairment; MMSE=Mini-Mental State Examination; MoCA=Montreal Cognitive Assessment; MRI=magnetic resonance imaging; PET=positron emission tomography; Qmci=Quick Mild Cognitive Impairment; SLUMS=Saint Louis University Mental Status.

CONTRAINDICATION

LEQEMBI is contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients of LEQEMBI. Reactions have included angioedema and anaphylaxis.

WARNINGS AND PRECAUTIONS AMYLOID-RELATED IMAGING ABNORMALITIES

Medications in this class, including LEQEMBI, can cause ARIA-E, which can be observed on MRI as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. ARIA can occur spontaneously in patients with AD, particularly in patients with MRI findings suggestive of cerebral amyloid angiopathy (CAA), such as pretreatment microhemorrhage or superficial siderosis. ARIA-H generally occurs with ARIA-E. Reported ARIA symptoms may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms usually resolve over time.

Incidence of ARIA

Symptomatic ARIA occurred in 3% and serious ARIA symptoms in 0.7% with LEQEMBI. Clinical ARIA symptoms resolved in 79% of patients during the period of observation. ARIA, including asymptomatic radiographic events, was observed: LEQEMBI, 21%; placebo, 9%. ARIA-E was observed: LEQEMBI, 13%; placebo, 2%. ARIA-H was observed: LEQEMBI, 17%; placebo, 9%. No increase in isolated ARIA-H was observed for LEQEMBI vs placebo.

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Treatment consideration: ApoE ε4 status

- **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 LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA[1]
- The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers[1]
- An FDA-authorized test for the detection of ApoE ε4 alleles to identify patients at risk of ARIA if treated with LEQEMBI is not currently available. Tests currently available to identify ApoE ε4 alleles may vary in accuracy and design[1]

ApoE ε4=apolipoprotein E ε4; ARIA=amyloid-related imaging abnormality.

WARNINGS AND PRECAUTIONS ARIA (cont'd)

Incidence of ICH

ICH >1 cm in diameter was reported in 0.7% with LEQEMBI vs 0.1% with placebo. Fatal events of ICH in patients taking LEQEMBI have been observed.

Risk Factors of ARIA and ICH

ApoE ε4 Carrier Status

Of the patients taking LEQEMBI, 16% were ApoE ε4 homozygotes, 53% were heterozygotes, and 31% were noncarriers. With LEQEMBI, ARIA was higher in ApoE ε4 homozygotes (LEQEMBI: 45%; placebo: 22%) than in heterozygotes (LEQEMBI: 19%; placebo: 9%) and noncarriers (LEQEMBI: 13%; placebo: 4%). Symptomatic ARIA-E occurred in 9% of ApoE ε4 homozygotes vs 2% of heterozygotes and 1% of noncarriers. Serious ARIA events occurred in 3% of ApoE ε4 homozygotes and in ~1% of heterozygotes and noncarriers. The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers.

Radiographic Findings of 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, have been identified as risk factors for ARIA. Patients were excluded from Clarity AD for the presence of >4 microhemorrhages and additional findings suggestive of CAA (prior cerebral hemorrhage >1 cm in greatest diameter, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of ICH.

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Step 4: Evaluate for pre-existing ARIA and initiate LEQEMBI[1]

- Obtain or review and document a recent baseline brain MRI prior to initiating treatment with LEQEMBI
- LEQEMBI can cause ARIA, characterized as ARIA-E, which can be observed on MRI as brain edema or sulcal effusions, and ARIA-H, which includes microhemorrhage and superficial siderosis. ARIA-H can also occur spontaneously in patients with AD

Intravenous initiation dosing regimen:

- The recommended initial dosage of LEQEMBI is 10 mg/kg once every 2 weeks. LEQEMBI must be diluted then administered as an IV infusion over approximately 1 hour
- If an infusion is missed, administer the next dose as soon as possible

Fax or email the following information to the infusion center with the infusion order form prior to first infusion:

- Patient's demographic and insurance information
- Patient's complete and current medication list

Follow-up infusions:

- After each infusion, ensure the patient/caregiver has confirmed an appointment for their next infusion in 2 weeks (see next step on page 9)

For assistance finding a location for your patients to receive their LEQEMBI treatment, visit the LEQEMBI locator tool.*

Visit LEQEMBILocator.com

You can also register your practice as an infusion center for LEQEMBI.

Visit infusioncenter.org/signin

*This tool is developed, hosted and maintained by NICA, an organization independent from Eisai. Eisai does not control or validate the content on the NICA Infusion Center Locator website. By making this link available, Eisai is not endorsing or recommending any particular infusion provider. The list of infusion providers searchable in the Locator is not comprehensive. Other infusion providers may be available to patients. An infusion site that would like to request to be added to the NICA Infusion Center Locator may contact NICA. When using the NICA Infusion Center Locator, it is the responsibility of the referring prescriber and/or patient to contact the site directly for any site-specific questions, including to confirm whether a site offers the prescribed medication, accepts the patient's insurance, and has schedule availability.

AD=Alzheimer's disease; ARIA=amyloid-related imaging abnormality; ARIA-E=amyloid-related imaging abnormality-edema; ARIA-H=amyloid-related imaging abnormality-hemosiderin deposition; IV=intravenous; MRI=magnetic resonance imaging.

WARNINGS AND PRECAUTIONS ARIA (cont'd)
Risk Factors of ARIA and ICH (cont'd)

Concomitant Antithrombotic or Thrombolytic Medication

- In Clarity AD, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. Most exposures were to aspirin. Antithrombotic medications did not increase the risk of ARIA with LEQEMBI. The incidence of ICH: 0.9% in patients taking LEQEMBI with a concomitant antithrombotic medication vs 0.6% with no antithrombotic and 2.5% in patients taking LEQEMBI with an anticoagulant alone or with antiplatelet medication such as aspirin vs none in patients receiving placebo.
- Fatal cerebral hemorrhage has occurred in 1 patient taking an anti-amyloid monoclonal antibody in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent.

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DILUTION[1]

- Each mL of solution contains 100 mg of lecanemab-irmb and arginine hydrochloride (42.13 mg), histidine (0.18 mg), histidine hydrochloride monohydrate (4.99 mg), polysorbate 80 (0.50 mg), and Water for Injection at an approximate pH of 5.0
- Before every infusion, calculate the dose (mg), the total volume (mL) of LEQEMBI solution required, and the number of vials needed based on the patient's actual body weight and the recommended dose of 10 mg/kg
- Use aseptic technique when preparing the LEQEMBI diluted solution for IV infusion
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Check that the LEQEMBI solution is clear to opalescent and colorless to pale yellow. Do not use if opaque particles, discoloration, or other foreign particles are present
- Remove the flip-off cap from the vial. Insert the sterile syringe needle into the vial through the center of the rubber stopper
- Withdraw the required volume of LEQEMBI from the vial(s) and add to an infusion bag containing 250 mL of 0.9% Sodium Chloride Injection, USP
- Each vial is for one-time use only. Discard any unused portion
- Gently invert the infusion bag containing the LEQEMBI diluted solution to mix completely. Do not shake
- After dilution, immediate use is recommended. If not administered immediately, store LEQEMBI refrigerated at 2°C to 8°C (36°F to 46°F) for up to 4 hours, or at room temperature up to 30°C (86°F) for up to 4 hours. Do not freeze

ADMINISTRATION[1]

- Visually inspect the LEQEMBI diluted solution for particles or discoloration prior to administration. Do not use if it is discolored, opaque, or foreign particles are seen
- Prior to infusion, allow the LEQEMBI diluted solution to warm to room temperature
- Infuse the entire volume of LEQEMBI diluted solution intravenously over approximately 1 hour through an IV line containing a terminal low-protein binding 0.2 micron in-line filter. Flush infusion line to ensure all LEQEMBI is administered
- Monitor for any signs or symptoms of an infusion-related reaction. 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, nonsteroidal anti-inflammatory drugs, or corticosteroids

IV=intravenous.

WARNINGS AND PRECAUTIONS ARIA (cont'd)
Risk Factors of ARIA and ICH (cont'd)

Concomitant Antithrombotic or Thrombolytic Medication (cont'd)

- Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI. 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 LEQEMBI.
- Caution should be exercised when considering the use of LEQEMBI in patients with factors that indicate an increased risk for ICH and, in particular, patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

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PATIENT COUNSELING INFORMATION[1]

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide).

Amyloid-Related Imaging Abnormalities

- Inform patients that LEQEMBI may cause Amyloid-Related Imaging Abnormalities or "ARIA". ARIA most commonly presents as a temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain
- Inform patients that most people with swelling in areas of the brain do not experience symptoms; however, some people may experience symptoms such as headache, confusion, dizziness, vision changes, nausea, aphasia, weakness, or seizure. Instruct patients to notify their healthcare provider if these symptoms occur
- Inform patients that serious symptoms of ARIA may occur, and that ARIA can be fatal
- Inform patients that events of intracerebral hemorrhage greater than 1 cm in diameter have been reported infrequently in patients taking LEQEMBI, and that the use of antithrombotic or thrombolytic medications while taking LEQEMBI may increase the risk of bleeding in the brain
- Notify patients that their healthcare provider will perform MRI scans to monitor for ARIA
- Inform patients that although ARIA can occur in any patient treated with LEQEMBI, there is an increased risk in patients who are ApoE ε4 homozygotes and that testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA
- Prior to testing, discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results
- Inform patients that if testing is not performed, it cannot be determined if they are ApoE ε4 homozygotes and at a higher risk for ARIA

Patient Registry

- Providers should encourage patients to participate in real world data collection (e.g. registries) to help further the understanding of Alzheimer's disease and the impact of Alzheimer's disease treatments. Providers and patients can contact Eisai at 888-274-2378 for a list of currently enrolling programs

Hypersensitivity Reactions

- Inform patients that hypersensitivity reactions, including angioedema and anaphylaxis have occurred in patients who were treated with LEQEMBI. Advise patients to seek immediate medical attention if they experience any symptoms of serious or severe hypersensitivity reactions

Infusion-Related Reactions

- Advise patients of the potential risk of infusion-related reactions, which can include flu-like symptoms, nausea, vomiting, and changes in blood pressure, the majority of which occur with the first infusion

AD=Alzheimer's disease; ApoE ε4=apolipoprotein E ε4; ARIA=amyloid-related imaging abnormality; MRI=magnetic resonance imaging.

WARNINGS AND PRECAUTIONS ARIA (cont'd)

Radiographic Severity With LEQEMBI

Most ARIA-E radiographic events occurred within the first 7 doses, although ARIA can occur at any time, and patients can have >1 episode. Maximum radiographic severity of ARIA-E with LEQEMBI was mild in 4%, moderate in 7%, and severe in 1% of patients. Resolution on MRI occurred in 52% of ARIA-E patients by 12 weeks, 81% by 17 weeks, and 100% overall after detection. Maximum radiographic severity of ARIA-H microhemorrhage with LEQEMBI was mild in 9%, moderate in 2%, and severe in 3% of patients; superficial siderosis was mild in 4%, moderate in 1%, and severe in 0.4% of patients. With LEQEMBI, the rate of severe radiographic ARIA-E was highest in ApoE ε4 homozygotes (5%) vs heterozygotes (0.4%) or noncarriers (0%). With LEQEMBI, the rate of severe radiographic ARIA-H was highest in ApoE ε4 homozygotes (13.5%) vs heterozygotes (2.1%) or noncarriers (1.1%).

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 14 weeks of treatment. Depending on ARIA-E and ARIA-H clinical symptoms and radiographic severity, use clinical judgment when considering whether to continue dosing or to temporarily or permanently discontinue LEQEMBI. If a patient experiences ARIA symptoms, 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.

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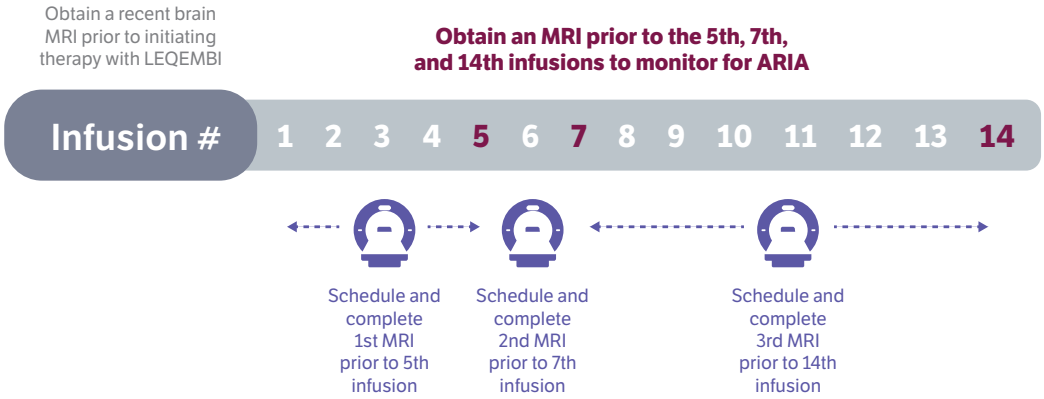
Step 5: Perform follow-up MRIs to monitor for ARIA[1]

- In clinical trials, MRIs were scheduled after patient tolerated the first dose well
- Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI, if indicated
- After initiation of treatment with LEQEMBI, obtain an MRI prior to the 5th, 7th, and 14th infusions
- If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment. (See page 10 for dosing interruptions)
- Communicate openly with key stakeholders about infusion and MRI scheduling and any safety concerns
- In patients who suspend dosing due to ARIA-E or mild to moderate ARIA-H, consider a follow-up MRI to assess for resolution or stabilization 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment



Step 6: Consider transitioning to maintenance dosing regimen after 18 months[1]

- After 18 months, once every 2 week dosing may be continued or transition to the maintenance dosing regimen of 10mg/kg once every 4 weeks
- No amyloid level testing is required to transition to maintenance therapy
- No additional MRIs are required, unless symptoms are experienced
- Duration of therapy is up to the discretion of the HCP and patient

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

WARNINGS AND PRECAUTIONS (cont'd)

HYPERSENSITIVITY REACTIONS

Hypersensitivity reactions, including angioedema, bronchospasm, and anaphylaxis, have occurred with LEQEMBI. 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 (IRRs)

- IRRs were observed—LEQEMBI: 26%; placebo: 7%—and most cases with LEQEMBI (75%) occurred with the first infusion. IRRs were mostly mild (69%) or moderate (28%). Symptoms included fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.
- In the event of an IRR, the infusion rate may be reduced or discontinued, and appropriate therapy initiated as clinically indicated. Consider prophylactic treatment prior to future infusions with antihistamines, acetaminophen, nonsteroidal anti-inflammatory drugs, or corticosteroids.

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RECOMMENDATIONS FOR DOSING INTERRUPTIONS FOR PATIENTS WITH ARIA-E[1]

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

Clinical symptom severity*	ARIA-E severity on MRI		
	Mild	Moderate	Severe
Asymptomatic	May continue dosing	Suspend dosing†	Suspend dosing†
Mild	May continue dosing based on clinical judgment		
Moderate or severe	Suspend dosing†		

*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.

†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.

› Use clinical judgment in considering whether to continue dosing in patients with recurrent ARIA-E

› There is no experience in patients who continued dosing through symptomatic ARIA-E or through asymptomatic but radiographically severe ARIA-E. There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E

RECOMMENDATIONS FOR DOSING INTERRUPTIONS FOR PATIENTS WITH ARIA-H[1]

› Recommendations for dosing in patients with ARIA-H depend on the type of ARIA-H and radiographic severity

Clinical symptom severity	ARIA-H severity on MRI		
	Mild	Moderate	Severe
Asymptomatic	May continue dosing	Suspend dosing‡	Suspend dosing§
Symptomatic	Suspend dosing‡		

‡Mild/moderate: 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.

§Severe: Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; use clinical judgment in considering whether to continue treatment or permanently discontinue LEQEMBI.

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

ARIA MRI CLASSIFICATION CRITERIA[1]

› The radiographic severity of ARIA associated with LEQEMBI was classified by the criteria shown below

ARIA type	Mild	Moderate	Severe
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortex white matter in 1 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	≤4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	≥10 new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	>2 areas of superficial siderosis

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

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Supply information and additional considerations for LEQEMBI®

SUPPLY[1]

LEQEMBI solution is supplied as a preservative-free, sterile, clear to opalescent, and colorless to pale yellow solution. LEQEMBI is supplied as one glass vial per carton as follows:

- 200 mg/2 mL (100 mg/mL) vial (with stopper and flip cap) – NDC 62856-212-01

- 500 mg/5 mL (100 mg/mL) vial (with stopper and flip cap) – NDC 62856-215-01

REFILLS

To reorder, contact your specialty distributor.

STORAGE AND HANDLING[1]

Unopened vial

- Store in refrigerator at 2°C to 8°C (36°F to 46°F)
- Store in the original carton to protect from light
- Do not freeze or shake

Diluted solution

- After dilution, immediate use is recommended
- If not administered immediately, store LEQEMBI refrigerated at 2°C to 8°C (36°F to 46°F) for up to 4 hours, or at room temperature up to 30°C (86°F) for up to 4 hours. Do not freeze

USE IN SPECIFIC POPULATIONS[1]

There are no adequate data on LEQEMBI use in

- Pregnant women
- Women who are breastfeeding
- Pediatric patients

For the geriatric population, in Study 1 and Study 2, the age of patients exposed to LEQEMBI 10 mg/kg every 2 weeks (n=1059) ranged from 50 to 90 years, with a mean age of 72 years; 81% were 65 years and older, and 39% were 75 years and older. No overall differences in safety or effectiveness of LEQEMBI have been observed between patients 65 years of age and older and younger adult patients.

SELECT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions reported in ≥5% with LEQEMBI and ≥2% higher than placebo were IRRs (LEQEMBI: 26%; placebo: 7%), ARIA-H (LEQEMBI: 14%; placebo: 8%), ARIA-E (LEQEMBI: 13%; placebo: 2%), headache (LEQEMBI: 11%; placebo: 8%), superficial siderosis of central nervous system (LEQEMBI: 6%; placebo: 3%), rash (LEQEMBI: 6%; placebo: 4%), and nausea/vomiting (LEQEMBI: 6%; placebo: 4%).

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Eisai Patient Support

Eisai Patient Support offers access and reimbursement support, including

- Benefits verification to assess product coverage
- Prior authorization assistance to understand requirements and payer decisions
- Appeal information
- Financial assistance information via the LEQEMBI® Copay Assistance Program

For more information, including how to enroll in Eisai Patient Support, visit EisaiPatientSupport.com.

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