LEQEMBI®
(lecanemab-irmb)

PERFORM TESTING

ASSESS AND MONITOR ARIA RISK

ARIA, amyloid-related imaging abnormalities.

Rachel is a real LEQEMBI patient.
People shown were compensated for their time, and information is accurate as of August 2025.

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

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. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Understanding ARIA and anti-amyloid treatment

Anti-amyloid treatments (AATs), including LEQEMBI®, can cause ARIA[1]

- ARIA can be classified as ARIA-E (edema) and ARIA-H (hemosiderin deposition)
- Typically appears early in treatment and is often asymptomatic, though rare serious or life-threatening events can occur. ARIA can be fatal
- ARIA may also arise spontaneously in Alzheimer's disease (AD)

Genetic testing recommendations may help assess ARIA[1,2]

Apolipoprotein E ε4 (ApoE ε4) testing is recommended to establish ARIA risk, but it is not required, and prescribers should inform patients that if genotype testing is not performed, they can still be treated with LEQEMBI[1]

- Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA; however, if genotype testing is not performed, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA[1]
- *ApoE* ε4 can be detected through genetic testing via blood or CSF samples[2]
- Patients with 1 or 2 copies of the ApoE ε4 specific allele have a higher risk of developing Alzheimer's disease and ARIA[1]
- Both carriers and noncarriers of the *ApoE* ε4 gene were included in the LEQEMBI trials[1]

Treatment recommendations for LEQEMBI are based on ARIA type, severity, and presence of symptoms, not ApoE ε4 status[1]

SELECT SAFETY INFORMATION

CONTRAINDICATION

Contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients. 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.

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Available ApoE ε4 tests

These labs are independent from Eisai. Eisai does not endorse or recommend any particular lab. This list is current as of September 18, 2025 and may change over time. It is the responsibility of the prescriber and/or patient to contact the lab directly for any lab-specific questions, including to confirm whether a lab offers a particular test, accepts the patient's insurance, or has schedule availability.

Lab	Test Name	Specimen Type	Other Code
Athena Diagnostics[3]	**ADmark® Alzheimer's Evaluation**	CSF and Whole Blood	178
Athena Diagnostics[4]	**ApoE Genotype Analysis and Interpretation (Symptomatic)**	Whole Blood	109
Precivity[5]	**PrecivityAD® (Beta-Amyloid 42-40 Ratio + ApoE ε4)**	Plasma	Contact Manufacturer
Labcorp[6]	**ApoE Alzheimer's Disease Risk**	Whole Blood	125536
Mayo Clinic Laboratories[7]	**ApoEG (Apolipoprotein E Genotyping), Blood**	Whole Blood	42315-2
Quest Diagnostics[8]	**Quest AD-Detect® Apolipoprotein E (ApoE) Isoform, Plasma**	Plasma	12563
Quest Diagnostics[9]	**Apolipoprotein E (ApoE) Isoform, CSF**	CSF	94626
Quest Diagnostics[9]	**Beta-Amyloid 42/40 Ratio and Apolipoprotein E (ApoE) Isoform, Panel CSF**	CSF	94628

ARIA-E, amyloid-related imaging abnormalities-edema; ARIA-H, amyloid-related imaging abnormalities-hemosiderin deposition; CSF, cerebrospinal fluid.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)

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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Imaging recommendations help you assess and manage ARIA risk

Proactively planning your patients' MRI schedule helps to facilitate a smooth monitoring process and timely implementation of patient management strategies[1]

The ARIA monitoring requirements are outlined in the Prescribing Information. LEQEMBI requires four follow-up MRIs after the initial scan. Additional MRIs may be needed if patients are presenting with symptoms[1]

For MRI ordering, please refer patients to a facility approved by their health plan and an MRI imaging facility that can take orders for consistent and specific imaging techniques

MRI, magnetic resonance imaging.

SELECT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (cont'd)
AMYLOID-RELATED IMAGING ABNORMALITIES (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.

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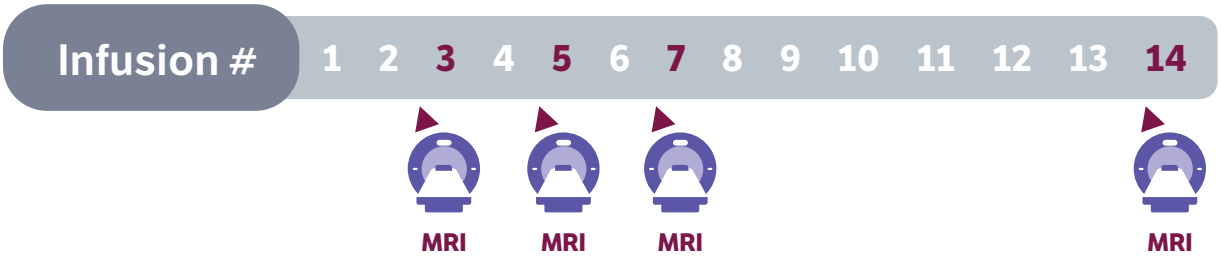
Routine MRI monitoring is used to evaluate the presence of ARIA

MRI monitoring and infusion schedule[1]

Obtain a recent brain MRI prior to initiating therapy with LEQEMBI[1]

In general, the MRI should be performed within approximately 1 week before the scheduled infusion of LEQEMBI and reviewed prior to proceeding with the infusion



- If a patient experiences symptoms suggestive of ARIA, a clinical evaluation should be performed, including an MRI if indicated
- In clinical trials, monitoring MRIs were scheduled after patients tolerated the first dose well
- Give neuroradiology adequate read and evaluation time when scheduling MRIs and yourself enough time to interpret the results
- Communicate openly with key stakeholders about infusion and MRI scheduling and any safety concerns

SELECT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (cont'd)
AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)
Risk Factors of ARIA and ICH (cont'd)
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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SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID-RELATED IMAGING ABNORMALITIES (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.

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.

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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SELECT SAFETY INFORMATION

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.

IRRs can occur during or after the completion of infusion. In the event of an IRR during the infusion, 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.

ADVERSE REACTIONS

- The most common adverse reactions reported in ≥5% with LEQEMBI infusion every 2 weeks 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%)
- Safety profile of LEQEMBI IQLIK for maintenance treatment was similar to LEQEMBI infusion. Patients who received LEQEMBI IQLIK experienced localized and systemic (less frequent) injection-related reactions (mild to moderate in severity)

LEQEMBI (lecanemab-irmb) is available:

- Intravenous infusion: 100 mg/mL
- Subcutaneous injection: 200 mg/mL

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Maintain consistency with your office protocols and neuroradiologists

- **Consider conducting MRIs with the same imaging sites**
- **Use a consistent protocol, field strength, and order type when ordering baseline and maintenance MRIs**
- **Work with neuroradiology to optimize MRI protocols and logistics, and determine if their preference is scheduling in blocks or individually**
- **Request that neuroradiologists document in the EMR the presence or absence of ARIA**
- **When ARIA are present, urgent communication should be made**

EMR, electronic medical record.

Implementing appropriate monitoring parameters may help give your patient a more coordinated treatment experience.

UnderstandingARIA.com

Explore more information on monitoring ARIA.

References: 1. LEQEMBI (lecanemab-irmb) [package insert]. Nutley, NJ: Eisai Inc. **2.** Konijnenberg E, Tijms BM, Gobom J, et al. APOE ε4 genotype-dependent cerebrospinal fluid proteomic signatures in Alzheimer's disease. *Alzheimers Res Ther*. 2020;12(1):65. doi:10.1186/s13195-020-00628-z **3.** Athena Diagnostics. ADmark® Alzheimer's evaluation. Accessed September 18, 2025. https://www.athenadiagnostics.com/view-full-catalog/admark-alzheimers-evaluation1 **4**. Athena Diagnostics. ADmark® ApoE genotype analysis and interpretation (symptomatic). Accessed September 18, 2025. https://www.athenadiagnostics.com/view-full-catalog/admark-apoe-genotype-analysis-and-interpretation-symptomatic1 **5.** Precivity. Summary of test and intended use population. Accessed September 18, 2025. https://precivityad.com/patients **6.** Labcorp. APOE Alzheimer's disease risk. Accessed September 18, 2025. https://www.labcorp.com/tests/125536/apoe-alzheimer-s-disease-risk **7.** Mayo Clinic Laboratories. Apolipoprotein E genotyping blood. Accessed September 18, 2025. https://www.mayocliniclabs.com/test-catalog/overview/35358#Fees-and-Codes **8.** Quest Diagnostics. Quest AD-Detect® apolipoprotein E (ApoE) isoform, plasma. Accessed September 18, 2025. https://jdos.nicholsinstitute.com/dos/chantilly/test/904059 **9.** Quest Diagnostics. Beta-amyloid 42/40 ratio and apolipoprotein E (ApoE) isoform panel, CSF. Accessed September 18, 2025. https://testdirectory.questdiagnostics.com/test/test-detail/94628/beta-amyloid-4240-ratio-and-apolipoprotein-e-apoe-isoform-panel-csf?cc=MASTER

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