LEQEMBI®
(lecanemab-irmb)

DIAGNOSE WITH CARE

CONFIRMING AMYLOID BETA (Aβ)

Lance 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.

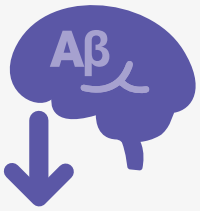
SELECT SAFETY INFORMATION

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.

Abnormal Aβ accumulation is a hallmark of Alzheimer's disease (AD)[1,2]



The accumulation of Aβ triggers pathological downstream events, including tau accumulation, leading to neurodegeneration[2]

Confirmation of the presence of Aβ pathology is one of the steps required to determine eligibility for LEQEMBI® using one of the testing options listed on the right, in addition to a full clinical evaluation[3]

Clinical tests to determine the presence of Aβ have been available for over a decade, including positron emission tomography (PET) and cerebrospinal fluid (CSF) obtained by lumbar puncture[4,5]

The pivotal Clarity AD trial evaluating LEQEMBI used PET or CSF biomarkers to confirm Aβ pathology, which may be covered under certain CMS policies[6,7]

Due to recent advances, blood testing is emerging as an accepted modality to confirm Aβ pathology[4]

CMS, Centers for Medicare and Medicaid Services.

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.

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.

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.

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Abnormal Aβ accumulation is a hallmark of Alzheimer's disease (AD)[1,2]

Amyloid PET

- Noninvasive[8]
- Allows direct visualization of amyloid plaques in the brain using specific radiotracers[8]
- Demonstrated high sensitivity and specificity in patients with confirmed AD[9]

CSF Testing

- Collected via lumbar puncture[4]
- May detect AD pathology earlier than neuroimaging biomarkers[10]
- Demonstrated high sensitivity and specificity in patients with confirmed AD[11]

Blood-Based Biomarkers (BBMs)

- Collected via a blood sample, and therefore less invasive[4]
- Can be rapidly scaled over time to meet testing needs[5]
- May serve as a triage and/or confirmatory tool to PET and CSF testing during initial AD evaluation[5]

Note: CMS removed NCD 220.6.20 from the Medicare National Coverage Determination (NCD) manual, effective October 13, 2023. This leaves Medicare coverage for an amyloid PET up to your regional Medicare Administrative Contractor, which may allow for multiple scans per patient lifetime.[12]

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

FDA-approved amyloid PET radiotracers[13]

Radiotracers	HCPCS code[14]
Amyvid®	A9586
Vizamyl™	Q9982
Neuraceq®	Q9983

HCPCS, Healthcare Common Procedure Coding System.

Scan to find the nearest PET scan center*

Disclaimer: This information is current as of September 17, 2025, but may change as more PET radiotracers become available.

*This tool is developed, hosted, and maintained by the Society of Nuclear Medicine and Molecular Imaging (SNMMI), an organization independent from Eisai. Eisai does not control or validate the content on the SNMMI brain imaging portal. By making this link available, Eisai is not endorsing or recommending any particular PET scan center. The list of centers searchable in the tool is not comprehensive. Other centers may be available to patients. It is the responsibility of the prescriber and/or patient to contact the center directly for any center-specific questions, including to confirm whether a center accepts the patient's insurance and has schedule availability.

How to order

- Identify an imaging center near you with the SNMMI imaging site finder
- Use a standardized order form

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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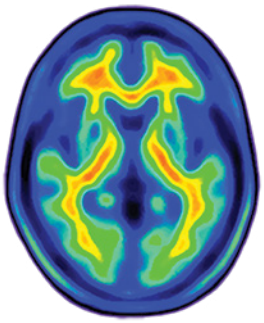
Confirm with PET

How to interpret the results (visual read)†

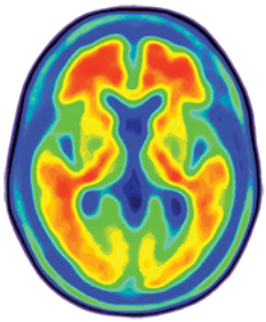
› High-resolution images are provided along with a report from a nuclear professional[15]

Negative scan



Negative scan indicates few plaques and is inconsistent with a neuropathological AD diagnosis.[16]

Positive scan



Positive scan indicates moderate to frequent amyloid neuritic plaques and is consistent with a neuropathological AD diagnosis, but may indicate other neurologic conditions or preclinical AD in cognitively unimpaired individuals.[16]

This research was originally published in *JNMT*. Mantel E, Williams J. *J Nucl Med Technol*. 2019;47(3):203-209. © SNMMI.[15]

†Alternatively, a quantitative method such as the standardized uptake value ratio (SUVR) can be implemented through software approved by Conformité Européenne (CE) and the Food and Drug Administration (FDA). Quantitative analysis and visual interpretation have generally been found to have similar sensitivity and specificity. However, quantitative analysis may be more sensitive to low levels of amyloid.[17-19]

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.

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Confirm with CSF

FDA-approved CSF test kits[20-24]

Test kit	Lab	Test ID
Fujirebio Lumipulse® G β-Amyloid Ratio (1-42/1-40) test	Labcorp	505560
	Mayo Clinic Laboratories	AMYR
Roche Elecsys® Alzheimer's Disease Evaluation, Spinal Fluid (Aβ, T-tau, p-Tau181, and p-Tau181/Aβ ratio)	Clinical Pathology Laboratories	3015
	Labcorp	484415
	Mayo Clinic Laboratories	ADEVL

Disclaimer: This information is current as of September 17, 2025, but may change as more CSF tests become available.

For more information or to order the FDA-authorized Lumipulse® G β-Amyloid Ratio (1-42/1-40) test, visit fujirebio.com or contact neuro@fdi.com. Please contact Roche for more information.

p-Tau181, blood tau phosphorylated at threonine 181; T-tau, total tau.

How to order

- For CSF testing, it is important to know proper handling protocols as well as how to accurately collect samples and what tube type to use
- Discuss the ordering process/workflow with your local clinical laboratory partner and/or review the package insert for the test

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

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Confirm with CSF

The Alzheimer's Association international guidance recommends the following protocol for frozen CSF samples[25]

Ensure frozen CSF samples are collected and transported appropriately[25]

At collection site

- Lumbar puncture: Remove first 2 mL CSF; directly collect CSF into a polypropylene LoB tube*
- No further handling needed (no centrifugation, mixing/ inverting, or tube transfer)

Transportation

- Freeze, transport, and store at -20° C or -80° C†

At the testing site

- Roller mixing after thawing, measure immediately
- Measure on high precision system: Aβ(1-42), Aβ(1-40), T-tau, p-Tau

*Follow manufacturer's recommendations for tube type and filling volume.
†Follow tube and assay manufacturer's instructions for use. Freezing of CSF for at least up to 2 weeks does not change Aβ concentrations.
LoB, low-bind.

How to interpret the results[25]

- CSF testing will identify the presence or absence of amyloid and indicate the ratio of individual biomarkers that were tested
- A lower CSF Aβ(1-42) concentration reflects its aggregation and sequestration into amyloid plaques in the brain

Note: Please refer to the Alzheimer's Association international guidance and manufacturers' labels for instructions and additional recommendations for CSF collection, storage, sample handling, and measurement techniques.

Confirm with BBMs

Advances in biomarker technology now allow clinicians to incorporate BBMs into the diagnostic workup for AD[26]

BBMs:

- Offer an **accessible, minimally invasive** way to help detect mild cognitive impairment (MCI) due to AD or mild AD—even in primary care settings[4,26]
- May **support earlier diagnosis**, inform risk assessment and prognosis, and guide patient management[4,26]
- Can **help stratify patients for treatment eligibility**, particularly in settings with limited diagnostic access or resources[26]
- BBMs are not intended as stand-alone diagnostic tests and should be integrated with patient/family history, brain imaging, routine laboratory tests, and other tests as appropriate[4,5,8]

Commercially distributed assays, including an FDA-cleared test option, may be available at the following labs[27]

Lab	Available test(s)	Lab	Available test(s)	Lab	Available test(s)
Quest		Mayo Clinic		Labcorp	

Reach out to your local lab provider for help in determining which test(s) may be most appropriate.

This information is current as of August 25, 2025, but may change as more BBMs become available.

Information provided for educational purposes only. This list is not an endorsement or recommendation by Eisai of any laboratory or test.

Discover the recent advancements in BBM test options at the Global CEO Initiative on Alzheimer's Disease (CEOi) Alzheimer's blood test performance database

SELECT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (cont'd)
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.

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Confirm with BBMs

How to order

- Before ordering a BBM test, a cognitive and/or functional assessment indicating mild cognitive impairment or dementia should be conducted[4,5,8]
- Blood work is a routine part of a patient visit; now you can add another blood test if you suspect AD after completing a cognitive workup
- Commercially available BBMs measure single analytes (such as Aβ40, Aβ42, or pTau 217) or a ratio of these analytes as they vary in diagnostic accuracy[5]

How to interpret

Sensitivity and specificity levels may vary depending on the test you select. Below are target profiles of BBMs for dementia specialists based on the CEOi recommendations.

Intended use	Criteria[5]	Results[5]
Triage	› Sensitivity should be ≥90% › Specificity should be ≥85% (75%-85% might be acceptable for AD specialists with a high capacity for follow-up amyloid PET or CSF testing)	› Positive test results indicate a high likelihood of amyloid pathology but require confirmation via amyloid PET or CSF testing › Negative test results indicate amyloid pathology is unlikely
Confirmatory	› Both sensitivity and specificity should be ≥90%	› Positive test results confirm amyloid pathology › Negative test results indicate amyloid pathology is unlikely

Aβ40, amyloid beta 40; Aβ42, amyloid beta 42; pTau 217, blood tau phosphorylated at threonine 217.

SELECT SAFETY INFORMATION

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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Confirm Aβ prior to initiation of LEQEMBI®

Visit leqembihcp.com for more information about LEQEMBI.

Lance is a real LEQEMBI patient and Liz is his care partner. People shown were compensated for their time, and information is accurate as of August 2025.

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