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

EARLY REFERRAL CAN MEAN EARLY INTERVENTION WITH LEQEMBI®[1,2]

Learn about how to identify mild cognitive impairment (MCI) due to Alzheimer's disease (AD)

FPO

Rachel is an actual LEQEMBI patient.
Patient information is accurate as of April 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 Select Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING.

Key facts about MCI due to AD

Decades before symptoms of MCI appear, abnormal amyloid accumulation begins in the brain[2]

~5-7 million people in the US aged ≥65 years may experience MCI due to AD[2]

~1 in 2 people remain undiagnosed[3]

60%-80% of dementia cases are AD, although "dementia" is used as a broad disease term[2]

Lance is an actual LEQEMBI patient.
Patient information is accurate as of April 2025.

MCI due to AD is a critical window for early intervention[2]

MCI due to AD is the earliest symptomatic stage[2]

The AD continuum[2,4,5]

Preclinical AD
Evidence of AD pathological biomarkers but no symptoms

Collectively known as early AD

MCI due to AD
Mild cognitive symptoms appear but may not interfere with daily activities

MCI due to AD appears most often as new yet subtle problems with memory, language, and thinking

Mild AD dementia
Cognitive symptoms interfere with some daily activities

Moderate AD dementia
Daily activities become more difficult, behavior may change, and some care partner assistance may be required

Severe AD dementia
Physical health is affected, verbal communication is diminished, and care partner assistance becomes necessary

Anti-amyloids are initiated in the early stages of AD

Therapeutic options include an emerging treatment class—anti-amyloids[2]

Anti-amyloid treatments

An emerging class that reduces amyloid-beta (Aβ) in the brain, which is an underlying pathology of AD[2]

Symptom management medications

Temporarily relieve AD symptoms related to memory, language, behavior, and thinking[2]

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Act quickly to identify, screen, and refer patients who may be appropriate for LEQEMBI®[2]

1) **Identify** MCI due to AD

- Patients in the MCI due to AD stage still perform activities of daily living independently, though they may **experience mild but detectable impacts** on more complex activities of daily life[2]
- Through direct observation and discussion with patients and care partners, make note of any **common symptoms of early cognitive decline.** For example[2]:
  - Frequent forgetfulness, poor judgment, and impaired decision-making
  - Inability to manage finances
  - Losing track of time

2) **Screen** for cognitive decline and well-being

Annual wellness visits present an opportunity to thoroughly assess your patients.

Conduct these workups related to cognitive decline:

- Evaluate performance based on MCI-sensitive tests (eg, MoCA, Mini-Cog©, AD8®, SLUMS)[6-9]
- Consider ordering blood biomarker tests for tau and/or Aβ*[10]

Evaluate and rule out other causes of MCI, besides AD, by leveraging:

Blood tests[11,12]**:**

- Rule out other causes of MCI with a complete blood count to test for medical conditions and comorbidities, including anemia, infection, diabetes, kidney, or liver disorders
- Other blood work may include labs to test for thyroid function, vitamin B_{12} deficiency, and elevated blood calcium levels

Neuroimaging[11,13]**:**

- Consider a magnetic resonance imaging (MRI) or CT scan to rule out tumors, evidence of small or large strokes, damage from severe head trauma, or fluid buildup in the brain

*Blood biomarker tests are not intended as stand-alone diagnostic tests and should be integrated with patient history and other appropriate testing.[10]

AD8, Eight-item Informant Interview to Differentiate Aging and Dementia; CT, computed tomography; MoCA, Montreal Cognitive Assessment; SLUMS, Saint Louis University Mental Status Examination.

3) **Refer** potential candidates for LEQEMBI to an AD specialist

Based on results and evidence from the workup, consider a referral.

Questions to consider for potential candidates for LEQEMBI:

- Are they concerned about recent changes in their memory?
- Are they accompanied by a family member or friend who shares their concerns?
- Are they motivated to take on treatment?

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SELECT SAFETY INFORMATION

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.

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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Select Safety Information (cont'd)

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.

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.

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%).

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

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.

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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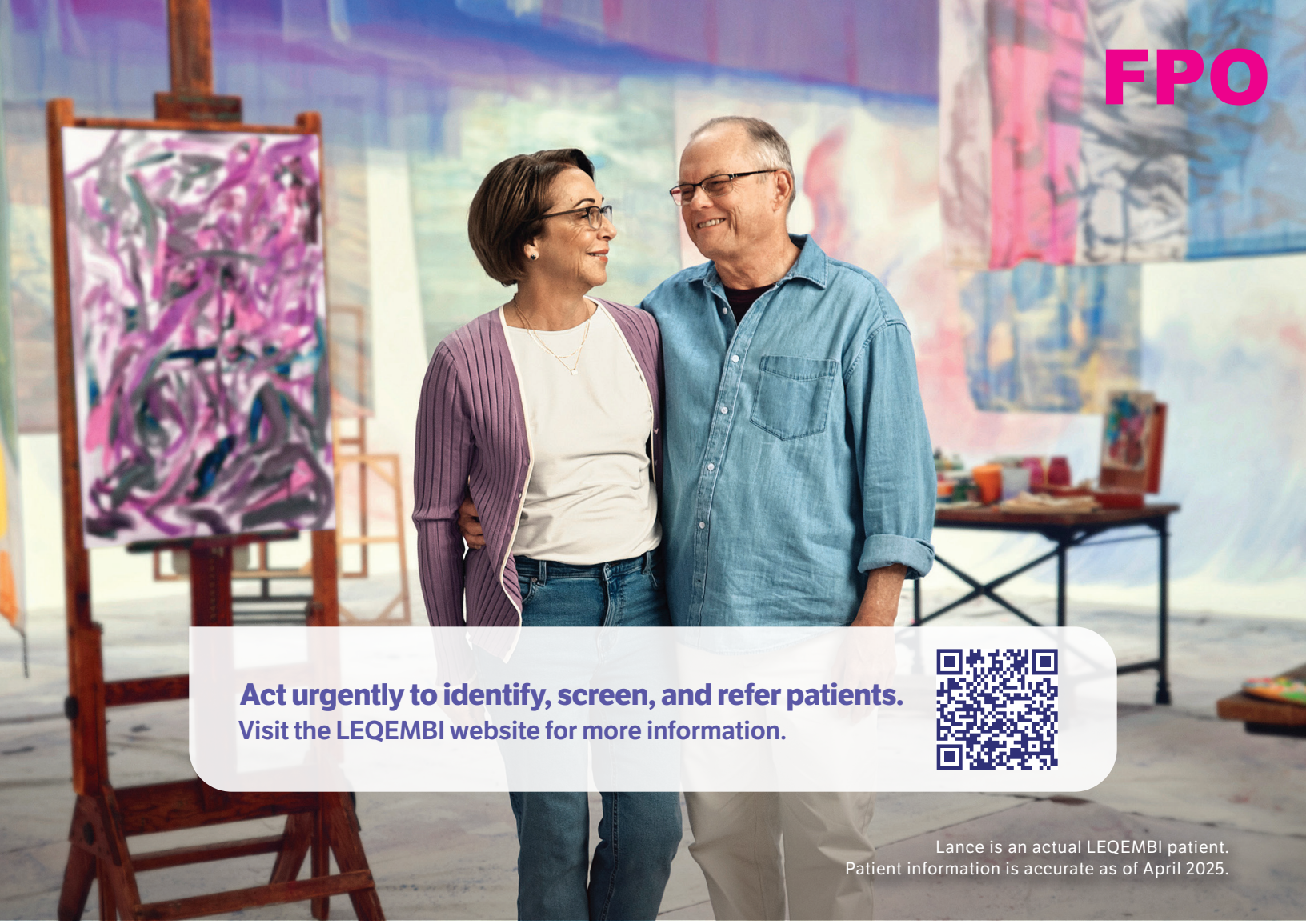

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References: 1. LEQEMBI (lecanemab-irmb) injection, for intravenous use [package insert]. Nutley, NJ: Eisai Inc; 2025. **2.** Alzheimer's Association. 2024 Alzheimer's disease facts and figures. *Alzheimers Dement*. 2024; 20(5):3708-3821. **3.** Cordell CB, Borson S, Boustani M, et al; Medicare Detection of Cognitive Impairment Workgroup. Alzheimer's Association recommendations for operationalizing the detection of cognitive impairment during the Medicare Annual Wellness Visit in a primary care setting. *Alzheimers Dement*. 2013;9(2):141-150. **4.** US Food and Drug Administration. Early Alzheimer's disease: Guidance for industry: developing drugs for treatment. March 2024. Accessed April 3, 2025. https://www.fda.gov/media/110903/download **5.** Jack CR Jr, Bennett DA, Blennow K, et al. NIA-AA research framework: toward a biological definition of Alzheimer's disease. *Alzheimers Dement*. 2018;14(4):535-562. **6.** Zhao Q, Du Z, Chen W, Zhang T, Xu Z. Advances in diagnosing mild cognitive impairment and Alzheimer's disease using ^{11}C-PIB- PET/CT and common neuropsychological tests. *Front Neurosci*. 2023;17:1216215. doi:10.3389/fnins.2023.1216215 **7.** Mini-Cog©. Scoring the Mini-Cog©. Quick screening for early dementia detection. Accessed April 3, 2025. https://mini-cog.com/scoring-the-mini-cog **8.** Galvin JE, Roe CM, Powlishta KK, et al. The AD8: a brief informant interview to detect dementia. *Neurology.* 2005;65(4):559-564. **9.** Tariq SH, Tumosa N, Chibnall JT, Perry MH III, Morley JE. Comparison of the Saint Louis University Mental Status Examination and the Mini-Mental State Examination for detecting dementia and mild neurocognitive disorder—a pilot study. *Am J Geriatr Psychiatry*. 2006;14(11):900-910. **10.** Angioni D, Delrieu J, Hansson O, et al. Blood biomarkers from research use to clinical practice: what must be done? A report from the EU/US CTAD task force. *J Prev Alzheimers Dis*. 2022;9(4):569-579. **11.** Porsteinsson AP, Isaacson RS, Knox S, Sabbagh MN, Rubino I. Diagnosis of early Alzheimer's disease: clinical practice in 2021. *J Prev Alzheimers Dis*. 2021;8(3):371-386. **12.** National Library of Medicine. Calcium blood test. MedlinePlus. Updated December 6, 2023. Accessed April 3, 2025. https://medlineplus.gov/lab-tests/calcium-blood-test/ **13.** Case Western Reserve University. Computed tomography (CT) of the brain: basics. Updated July 4, 2016. Accessed April 3, 2025. https://case.edu/med/neurology/NR/CT%20Basics.htm

Eisai

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