

LEQEMBI IQLIK®
(lecanemab-irmb)
Injection

GETTING STARTED GUIDE

FOR INITIATION

500 mg once-weekly (two 250 mg single-dose, prefilled autoinjectors)

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 full Prescribing Information for LEQEMBI, including Boxed WARNING.

SUPPORT TO HELP PATIENTS GET STARTED ON LEQEMBI IQLIK®

LEQEMBI Companion®

The LEQEMBI Companion® program can offer information to help patients access treatment, understand their insurance coverage, and identify financial support for eligible patients.

- Enroll patients in the LEQEMBI Companion program to receive a summary of your patient's insurance benefits for LEQEMBI®
- The enrollment form serves as the prescription, enabling direct triage to the appropriate in-network specialty pharmacy or to the IDN pharmacy of the patient's choice

Enrollment Form
leqembienrollment.com

Eisai Access & Reimbursement Managers (ARMs)

Support access with answers to questions about patient access, coverage, and reimbursement

For patients with **Medicare Part D** insurance[2]:

In 2027, **the maximum patient out-of-pocket cost** for covered Medicare Part D drugs is $2,400. Once this amount is reached, patients will pay $0 for the rest of the calendar year. The Medicare Part D coverage gap has been eliminated.*

*The cap adjusts annually. For 2026, the OOP cost for Medicare Part D is $2,100.

The Medicare Prescription Payment Plan helps eligible patients who opt in manage out-of-pocket prescription drug costs by spreading payments over the calendar year (January–December).

Visit Medicare.gov for more information

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.

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

STEPS FOR GETTING PATIENTS STARTED ON LEQEMBI IQLIK® FOR INITIATION

SUBMIT PRESCRIPTION

BENEFITS VERIFICATION

Will determine if:

- Specified specialty pharmacy is needed
- Prescription is covered
- Medical exception or prior authorization is required

SUBMIT MEDICAL EXCEPTION OR PRIOR AUTHORIZATION

APPROVED

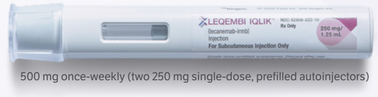
DENIED

Submit an appeal

If denied, coordinate with the specialty pharmacy to determine if an appeal is appropriate and what supporting information is required

SPECIALTY PHARMACY SCHEDULES DELIVERY (upon approval)

Note: Remind patients to be ready for a phone call, as specialty pharmacies may call from an unknown number



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PATIENT INITIATION AND ONGOING TREATMENT JOURNEY[1]

- LEQEMBI IQLIK may be administered by a patient or care partner after the HCP provides supervision for at least 2 consecutive subcutaneous doses and determines that administration of LEQEMBI IQLIK by the patient or care partner is appropriate
  - Continue to periodically reassess the appropriateness for subcutaneous treatment
  - Counsel patients to monitor for side effects, including injection-site reactions
- Patients can view step-by-step injection demonstration in the Instructions for Use video located on LEQEMBI.com and may receive a Welcome Kit that includes the What to Expect Treatment Tracker and Demo Kit
- Obtain a recent baseline brain MRI prior to initiating treatment and after months 1, 2, 3, and 6 of treatment (eg, prior to the *3rd* dose for intravenous route or *5th* dose for subcutaneous route)[1]
  - In general, the MRI should be performed within approximately one week before the infusion or injection of LEQEMBI and reviewed prior to proceeding with the infusion or injection
  - Throughout treatment, if a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated
  - If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms

Visit LeqembiHCP.com
to explore injection resources for your patients.

ARIA, amyloid-related imaging abnormalities; HCP, health care provider MRI, magnetic resonance imaging.

Example prescription for LEQEMBI IQLIK

Rx: *LEQEMBI 500 mg (2 x 250 mg)/1.25 mL (200 mg/mL) single-dose prefilled IQLIK autoinjector*

Sig: *Inject 500 mg subcutaneously once weekly. Administer as two 250 mg injections*

Disp: [#8]

Things to consider

- Provide clinical oversight throughout treatment
- If you practice within an Integrated Delivery Network, hospital, or clinic with an integrated specialty pharmacy, they may have their own established processes for managing the steps outlined in this resource
- Use your clinical judgment to determine the appropriate amount of refills for your patient
  - You may consider writing a month at a time to help manage MRI compliance
- Providers may submit prescriptions directly to the specialty pharmacy through available prescribing channels, including EHR e-prescribing workflows and other approved electronic or paper-based submission methods
  - To support efficient processing and minimize delays, providers should include all relevant clinical documentation and respond promptly to specialty pharmacy outreach, requests for information, and clarification inquiries

Eisai has contracted with CareMed and Walgreens to provide the following support for patients:

- Shipment of a LEQEMBI Welcome Kit, including a demonstration device and educational resources designed to help patients understand what to expect when starting and continuing LEQEMBI IQLIK
- For patients who opt in, ongoing treatment education during the first 6 months of therapy to support adherence, answer questions, reinforce treatment expectations, provide supplemental self-administration injection education, and address individual patient and care partner informational needs. Education is provided virtually via phone or video
- As part of these educational interactions, patients receiving medication through Eisai's Specialty Pharmacy Network (CareMed and Walgreens) may also receive MRI reminders, as appropriate

CareMed Specialty Pharmacy
caremedsp.com/contact/

Dedicated Line: 1-888-310-1766
Fax: 1-877-542-2731
Hours of operation: Monday-Friday, 9 AM-6 PM (ET)

Address
1985 Marcus Ave, Suite 130, New Hyde Park, NY 11042

Walgreens Specialty Pharmacy
walgreensspecialtyrx.com/specialty-home

Dedicated Line: 1-866-266-8037
Fax: 1-888-570-4700
Hours of operation: Monday-Friday, 8 AM-8 PM (ET)

Address
130 Enterprise Drive
Pittsburgh, PA 15275

*LEQEMBI IQLIK is available through the LEQEMBI IQLIK Specialty Pharmacy Network (CareMed and Walgreens) and through certain hospital and integrated delivery network specialty pharmacies (IDN SPs). Check with your institution's pharmacy to determine if IQLIK is available.

LEQEMBI IQLIK may also be obtained from certain hospital and IDN specialty pharmacies that are not part of the LEQEMBI Specialty Pharmacy Network. Other pharmacies may provide support. Patients are encouraged to speak with their pharmacy about what to expect.

Eisai cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record.

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.

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

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

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LEQEMBI® (lecanemab-irmb)

SELECT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (cont'd)
AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)
Concomitant Antithrombotic or Thrombolytic Medication (cont'd)

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.

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%)
- The safety profile of subcutaneous LEQEMBI was similar to intravenous infusion. Subcutaneous dosing was associated with mostly localized (erythema, induration, swelling, heat, pain, pruritus, rash, ecchymosis, nodule, and hematoma) and less frequent systemic (headache, chills, fever, and fatigue) injection-related reactions, majority at first dose when initiating therapy. Localized reactions that were recurrent and/or delayed were observed. Severe localized reactions and cases leading to dose discontinuation or interruption occurred.

LEQEMBI (lecanemab-irmb) is available:

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

References: 1. LEQEMBI (lecanemab-irmb) [package insert]. Nutley, NJ: Eisai Inc. **2.** Centers for Medicare & Medicaid Services. Costs for Medicare drug coverage. Medicare.gov. Updated September 24, 2026. Accessed September 24, 2026. https://www.medicare.gov/health-drug-plans/part-d/basics/costs **3.** Medicare. Fact Sheet. What's the Medicare Prescription Payment Plan? Accessed June 29, 2026. www.medicare.gov/publications/12211-whats-the-medicare-prescription-payment-plan.pdf

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

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