LEQEMBI® IQLIK™ (lecanemab-irmb) Offers Patient-Centric Alzheimer's Care for US Patients and Families Living with Early Alzheimer's Disease

Eisai's Approach to U.S. Pricing for LEQEMBI IQLIK

At Eisai, our human health care (*hhc*) mission is to give our first thought to patients and their families, and to increase the benefits that health care provides. This guiding philosophy informs every decision we make including how we advance patient-centric innovations, provide patient support programs, and responsibly determine the societal value and pricing of our medicines. We accomplish this by considering patient outcomes, caregiver impact, and overall health system efficiency, consistent with published economic analyses.

LEQEMBI IQLIK is the first and only anti-amyloid therapy designed to offer an at-home injection that patients with Mild Cognitive Impairment (MCI) due to Alzheimer's disease (AD) or mild dementia (collectively referred to as early AD) may use for maintenance therapy. LEQEMBI IQLIK provides an at-home treatment option for health care providers (HCPs) and patients with early AD who have completed 18 months of intravenous (IV) therapy with LEQEMBI. The weekly autoinjector (SC-AI) takes approximately 15 seconds to administer, offering flexibility to patients, care partners, and HCPs, including:

- LEQEMBI IQLIK can be administered in the comfort and privacy of one's own home, and patients and care partners can travel with the SC-AI and still stay on schedule, allowing for continuous treatment of this progressive, chronic disease.
- An at-home maintenance option expands infusion center capacity. Transitioning patients to LEQEMBI IQLIK for maintenance treatment makes more infusion chairs available for new, eligible patients to begin initiation treatment.
- By offering subcutaneous maintenance therapy as an option, LEQEMBI IQLIK supports long-term disease management, aligns treatment delivery with the needs of patients and care partners, and may help to reduce care-related expenses.

Click here for a link to the press release announcing the FDA approval of LEQEMBI IQLIK

U.S. Societal/Economic Burden[1]

An estimated 7.2MM Americans aged 65 and older are currently living with AD, the most common cause of dementia. The annual number of new cases of AD and other dementias is expected to double by 2050, with the total number of patients with AD reaching 13MM. The seventh leading cause of death in the US, AD is also one of the costliest conditions to society. AD places a substantial burden on the healthcare system, increasing demand for medical services, long-term care, and specialized support; the economic impact extends beyond families to the broader economy, with high costs tied to care, lost productivity, and public health expenditures.

- In the US, financial strain among care partners is common, with costs related to medical appointments, testing, long-term care, and lost income when care partners must reduce work hours or leave jobs.

- In 2024, for example, unpaid caregivers of people with AD or other dementias provided care valued at more than $5B in each of 27 states. In each of the four most populous states (California, Texas, Florida, and New York), caregivers provided care valued at more than $22B. This caregiving burden underscores the importance of innovations that reduce treatment-related time and travel demands, such as at-home administration.

Value of LEQEMBI to U.S. Healthcare System

According to a report from the Alzheimer's Association, "Changing the Trajectory of Alzheimer's Disease: How a Treatment by 2025 Saves Lives and Dollars", the total costs of care in the U.S. from all payers (i.e., Medicare, Medicaid, out-of-pocket and other payers), would increase from $340B in 2025 to $1.1T in 2050 if no treatment existed to delay the disease.[2] LEQEMBI offers meaningful benefits to patients with early AD, by slowing disease progression, including cognitive and functional decline, to help patients maintain who they are for longer.[3]

LEQEMBI IQLIK represents a patient centric innovation that will further advance Alzheimer's care and provide benefits to the U.S. healthcare system. This was demonstrated in a recently published academic paper, "Societal Costs and Efficiency of Subcutaneous versus Intravenous Lecanemab in Early Alzheimer's Disease: A U.S. Cost Comparison Model," which was published in the peer-reviewed scientific journal *Neurology and Therapy.*

According to this analysis, patients could save between $72,891 and $80,925 over four years, while projected health system savings could range from $3.16B to $3.71B, assuming current treatment rates with LEQEMBI and uptake of LEQEMBI IQLIK. These savings are driven by reduced treatment costs attributed to a more efficient fixed dose autoinjector delivery, lower administrative costs, and reduced time spent by healthcare providers, patients, and care partners. In addition, the option of at-home administration contributes $24,102 to $32,136 in quality-of-life related savings.[4] Click here to access the full paper.

US Pricing

The Wholesale Acquisition Cost (WAC) for LEQEMBI IQLIK will be set at $375 per autoinjector. It is important to note, WAC is the list price and does not reflect what patients typically pay. Patient's out-of-pocket cost for LEQEMBI IQLIK will vary based on individual insurance. Patients covered under Medicare Part D plans are subject to an annual out-of-pocket cap on their total combined spending on covered drugs. The current annual cap is $2,000, meaning when covered by Part D plans, out-of-pocket cost for LEQEMBI IQLIK for Medicare beneficiaries will be no more than $2,000, and may be less for many patients. Eisai's pricing reflects the balance between enabling broad patient access, supporting long-term sustainability of the healthcare system, and recognizing the demonstrated societal value of subcutaneous administration.

Patient Support Programs

Eisai is committed to ensuring that appropriate patients have access to LEQEMBI. Eisai offers several support programs to help patients and care partners. Dedicated Patient Navigators will work directly with patients and families to navigate treatment and coverage for eligible and appropriate patients and to help explain what to expect regarding insurance coverage, co-pay, and patient access programs. For patients prescribed LEQEMBI IQLIK, injection education support will also be available. To learn more visit LEQEMBI.com, call 1-833-4-LEQEMBI (1-833-453-7362), Monday-Friday, 8 a.m. to 8 p.m. Eastern Time.

In addition, to support access to LEQEMBI for certain patients who need help paying for their medicines, Eisai's Patient Assistance Program (PAP) will provide LEQEMBI and LEQEMBI IQLIK at no cost, for eligible uninsured and underinsured patients, including Medicare beneficiaries, who meet financial need and other program criteria.

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.

IMPORTANT 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.**

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.

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%).

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%)
- 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

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

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References

1. Alzheimer's Association. (2025). *2025 Alzheimer's disease facts and figures*. *Alzheimer's & Dementia, 21*(5). Available at: https://www.alz.org/getmedia/ef8f48f9-ad36-48ea-87f9-b74034635c1e/alzheimers-facts-and-figures.pdf. Accessed August 24, 2025.
2. Alzheimer's Association. (2015). *Changing the trajectory of Alzheimer's disease: How a treatment by 2025 saves lives and dollars*. Alzheimer's Association. https://www.alz.org/getmedia/318df5d0-b248-421e-a613-6bc384e9c884/changing-the-trajectory-r.pdf. Accessed August 24, 2025.
3. van Dyck CH, Swanson CJ, Aisen P, Bateman RJ, Chen C, Gee M, Kanekiyo M, Li D, Reyderman L, Cohen S, Froelich L, Katayama S, Sabbagh M, Vellas B, Watson D, Dhadda S, Irizarry M, Kramer LD, Iwatsubo T. Lecanemab in Early Alzheimer's Disease. N Engl J Med. 2023 Jan 5;388(1):9-21. https://doi: 10.1056/NEJMoa2212948. Epub 2022 Nov 29. PMID: 36449413.
4. Tahami Monfared, A.A., Barrows, S., Fox, L. *et al.* Societal Costs and Efficiency of Subcutaneous versus Intravenous Lecanemab in Early Alzheimer's Disease: A U.S. Cost Comparison Model. *Neurol Ther* (2025). https://doi.org/10.1007/s40120-025-00790-2.