For patients with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease (AD)

LEQEMBI®
(lecanemab-irmb)

YOUR GUIDE FROM EARLY DIAGNOSIS TO TREATMENT

An overview of the LEQEMBI® treatment pathway for early Alzheimer's disease (AD)



REBECCA

LEQEMBI PATIENT SINCE 2023

Information is accurate as of August 2026.
Individuals were compensated.

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.

Steps from diagnosis to treatment with LEQEMBI®

Step 1

Assess patient eligibility and readiness for LEQEMBI

Step 2

Evaluate ARIA risk and prepare to start treatment

Step 3

Initiate treatment and monitor



Kamala, LEQEMBI patient since 2024.
Information is accurate as of August 2026.
Individuals were compensated.

ARIA, amyloid-related imaging abnormalities.

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.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Why identification and early intervention with LEQEMBI® matters

The underlying pathology of AD begins years before the symptoms appear[1]

In the early stages of AD, mild cognitive symptoms are present. However, patients may not recognize them. Family or friends may be the first to notice these subtle changes and help their loved ones seek medical care.[1]

Mild cognitive impairment (MCI) due to AD presents as subtle problems with memory, language, and thinking that can be confused with normal signs of aging.[1]

When you recognize the warning signs of MCI due to AD, you have a better chance of early intervention and implementing appropriate treatment options.[1]

MCI due to AD and mild AD dementia are different stages and critical points for intervention[1]

Alzheimer's disease continuum[1]

Preclinical AD	MCI due to AD	Mild AD dementia	Moderate AD dementia	Severe AD dementia
Evidence of AD pathological biomarkers but no symptoms	Mild cognitive symptoms appear but may not interfere with daily activities	Cognitive symptoms interfere with some daily activities	Daily activities become more difficult, behavior may change, and some care partner assistance may be required	Physical health is affected, verbal communication is diminished, and care partner assistance becomes necessary



The earlier MCI due to AD and mild AD dementia are diagnosed and treated, the greater the opportunity for benefit.[1]

AD, Alzheimer's disease; MCI, mild cognitive impairment.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

LEQEMBI® (lecanemab-irmb)

Step 1

Assess patient eligibility and readiness for LEQEMBI®

Proactive steps to diagnose AD at the earliest symptomatic stages

CHECK FOR COGNITIVE IMPAIRMENT[2-5]



- Patient history/informant observations
- Physical/neurological exams
- Assess the patient's function
  - A functional assessment may be required to start an eligible patient on therapy
  - Consider using a functional assessment to identify daily activity: FAQs, FAST, and/or CDR-SB
- While no test represents a gold standard, the following are examples of neurocognitive tools that are sensitive to MCI due to AD and/or mild AD dementia and can aid in early identification—MoCA, Qmci screen, MMSE, Mini-Cog©, SLUMS, and AD8

RULE OUT NON-AD CAUSES[2,6,7]



- Lab tests can rule out other causes such as vitamin B_{12} deficiency and thyroid diseases
- Medications/comorbidities could be underlying causes
- CT scans or MRIs can rule out other causes such as tumors, evidence of small or large strokes, damage from severe head trauma, or fluid buildup in the brain

CONFIRM AD DIAGNOSIS[8-10]



- Biomarker-confirmed AD diagnosis allows for Aβ-targeting therapy in appropriate patients
- CSF, PET, or BBM confirms Aβ pathology

Aβ, amyloid beta; AD, Alzheimer's disease; AD8, Eight-item Informant Interview to Differentiate Aging and Dementia; BBM, blood-based biomarker; CDR-SB, Clinical Dementia Rating-Sum of Boxes; CSF, cerebrospinal fluid; CT, computed tomography; FAQ, Functional Activities Questionnaire; FAST, Functional Assessment Staging Tool; MoCA, Montreal Cognitive Assessment; MCI, mild cognitive impairment; MMSE, Mini-Mental State Examination; MRI, magnetic resonance imaging; PET, positron emission tomography; Qmci, Quick mild cognitive impairment; SLUMS, Saint Louis University Mental Status Examination.

SELECT SAFETY INFORMATION
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.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Step 1 Assess patient eligibility and readiness for LEQEMBI® (cont'd)

Amyloid PET

- Accessibility limitations[11]
- Demonstrated high sensitivity and specificity to detect amyloid plaques in patients with clinically diagnosed AD[11]
- Exposes the patient to radiation[12]

FDA-approved amyloid PET radiotracers[13]

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

HCPCS, Healthcare Common Procedure Coding System.
Disclaimer: This information is current as of August 5, 2026 but may change as more PET radiotracers become available.

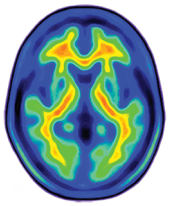
Click here to find the nearest PET scan center

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 the results are interpreted (visual read)*

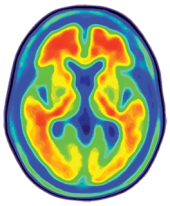
- High-resolution images are provided to the prescribing physician, along with a report from a nuclear professional[15]

Negative scan



Negative scan indicates few plaques, which 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. However, this may also 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;47:203-209. © SNMMI.[15]

*Alternatively, a quantitative method such as the standardized uptake value ratio or the corresponding Centiloid (CL) scale can be implemented through software approved by Conformité Européenne and the Food and Drug Administration. 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]

Note: CMS removed NCD 220.6.20 from the Medicare National Coverage Determination 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.[20]

CMS, Centers for Medicare and Medicaid services.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

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Step 1 Assess patient eligibility and readiness for LEQEMBI® (cont'd)

CSF testing



- Collected via lumbar puncture[10]
- May detect AD pathology earlier than neuroimaging biomarkers[21]
- Demonstrated high sensitivity and specificity in patients with confirmed AD[21,22]

How the results are interpreted

- CSF testing will identify the presence or absence of amyloid and indicate the ratio of individual biomarkers that were tested[21]
- A lower CSF Aβ (1-42) concentration reflects its aggregation and sequestering into amyloid plaques in the brain[21]

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

FDA-approved CSF test kits[23-27]

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 July 27th, 2026, 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.

Aβ, amyloid beta; AD, Alzheimer's disease; CSF, cerebrospinal fluid; p-Tau181, blood tau phosphorylated at threonine 181; T-tau, total tau.

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.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Step 1 Assess patient eligibility and readiness for LEQEMBI® (cont'd)

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

The Alzheimer's Association international guidance recommends the following protocol for frozen CSF samples[21]

Ensure frozen CSF samples are collected and transported appropriately[21]

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.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

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Step 1 Assess patient eligibility and readiness for LEQEMBI® (cont'd)

Blood-based biomarkers



- Collected via a blood sample, and therefore less invasive[10]
- Can be rapidly scaled over time to meet testing needs[28]
- May serve as a triage and/or confirmatory tool to PET and CSF during initial AD evaluation[28]

Interpreting the results

Sensitivity and specificity levels may vary depending on the test you select. On the right are target profiles of BBMs for dementia specialists based on the Global CEO Initiative on Alzheimer's Disease (CEOi) recommendations.

Commercially distributed assays, including FDA-cleared testing options may be available at the following labs[29]

p-tau 217 is emerging as the leading biomarker for Alzheimers pathology.[30]

Lab			
Quest	Labcorp	Mayo Clinic	C2N Diagnostics

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

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

This information is current as of July 23rd, 2026, but may change as more BBMs become available.

AD, Alzheimer's disease; BBM, blood-based biomarker; CSF, cerebrospinal fluid; PET, positron emission tomography p-tau217, tau protein phosphorylated at threonine at threonine 217.

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.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Step 1 Assess patient eligibility and readiness for LEQEMBI® (cont'd)

Intended use	Criteria[28]	Results[28]
RULE OUT *Triage*	› Sensitivity should be ≥90% › Specificity should be ≥85% (75% to 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
RULE IN *Confirmatory*	› Both sensitivity and specificity should be ≥90%	› Positive test results confirm amyloid pathology › Negative test results indicate amyloid pathology is unlikely

Learn more about specific BBMs on the CEOi Alzheimer's blood test performance database

Clinical practice guidelines for use of BBMs were published in July of 2025 by the Alzheimer's Association. Learn more at: https://alz-journals.onlinelibrary.wiley.com/doi/10.1002/alz.70535. If there is a question about the blood test satisfying payer coverage requirements before initiating any therapeutic agent, please reach out to the specific payer for that determination.

When making critical treatment decisions, talk with your patients about their readiness for starting LEQEMBI®

- Individual **patient factors and circumstances** must be taken into account, including treatment goals, appropriate route of administration, and availability for repeated MRI scans
- Assess **nonclinical considerations** that may contribute to treatment success, including:
  - Patients motivated to seek treatment
  - Presence of care partner that can help navigate treatment
  - Patients who are willing to commit to MRI and injection or infusion schedules


Leonard, LEQEMBI patient since 2023.
Information is accurate as of August 2026.
Individuals were compensated.

MRI, magnetic resonance imaging.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

LEQEMBI® (lecanemab-irmb)

Step 2a

Evaluate ARIA risk and prepare to start treatment

What is ARIA?

ARIA is a potential side effect of monoclonal antibodies, like LEQEMBI®, and can occur spontaneously in patients with AD.[31]

LEQEMBI can cause ARIA, which can present in 2 ways:

ARIA-E[31]

Presents as temporary swelling in areas of the brain and usually resolves over time

ARIA-H[31]

Presents as small spots of bleeding in or on the surface of the brain; infrequently, larger areas of bleeding in the brain can occur

ARIA usually occurs early in treatment and is mostly asymptomatic[31]

- Symptomatic ARIA occurred in 3% (29/898) and serious symptoms associated with ARIA occurred in 0.7% (6/898) of patients treated with LEQEMBI. ARIA can be fatal[31]
- Clinical symptoms associated with ARIA resolved in 79% (23/29) of patients during the period of observation[31]
- ARIA-H that occurred with ARIA-E tended to occur early (within 6 months)[32]
- Serious events of ARIA occurred in 3% of ApoE ε4 homozygotes and in ~1% of the heterozygotes and noncarriers[31]

Incidence of ARIA[31,32]

ARIA incidence	LEQEMBI (n=898) % (n)	Placebo (n=897) % (n)
ARIA-E or ARIA-H*	21 (191)	9 (84)
ARIA-E	13 (113)	2 (15)
ARIA-H	17 (152)	9 (80)
Isolated ARIA-H	8.9 (80)	7.8 (70)

*Including asymptomatic radiographic events.[31]

ARIA-E: ARIA with edema can be observed on MRI as brain edema or sulcal effusions.[31]

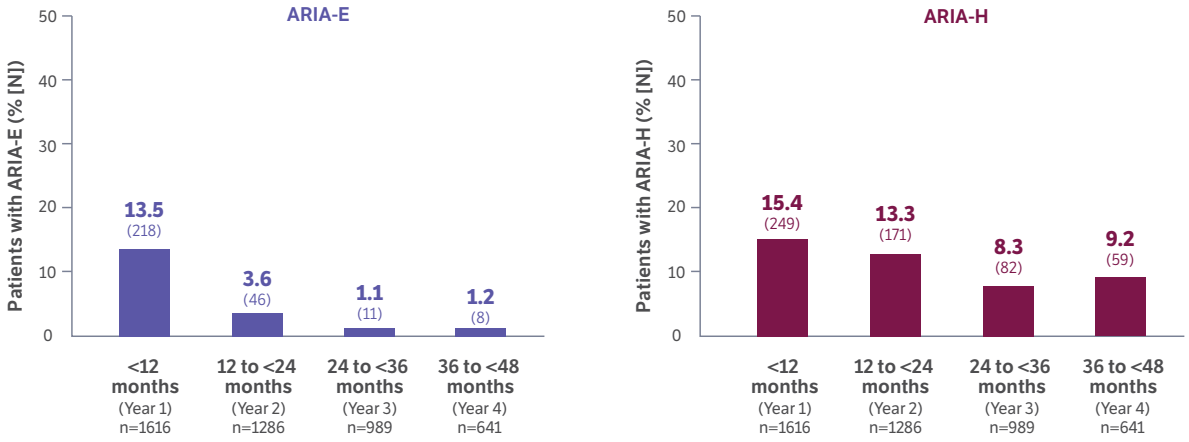
ARIA-H: ARIA with hemosiderin deposition includes microhemorrhage and superficial siderosis.[31]

AD, Alzheimer's disease; ApoE ε4, apolipoprotein E ε4; ARIA, amyloid-related imaging abnormalities; ARIA-E, amyloid-related imaging abnormalities-edema; ARIA-H, amyloid-related imaging abnormalities-hemosiderin deposition.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

The incidence of ARIA decreased after 12 months as patients continued therapy with LEQEMBI®*[33]

Clarity AD Core period and LTE: Rates of ARIA-E and ARIA-H by years[33]



*Infusion-only data.[33]
Cutoff: March 31, 2025.[33]
The LTE study is ongoing.[34]

Imaging requirements and genetic testing recommendations are in place to help you assess and manage ARIA risk[31]



- A baseline MRI is required to initiate LEQEMBI treatment
- Additionally, obtain an MRI after 1 month (e.g., prior to the *3rd* dose for the intravenous route or *5th* dose for the subcutaneous route), 2 months, 3 months, and 6 months of treatment
- ApoE ε4 testing is recommended to establish ARIA risk, but is not required
- Throughout treatment, if a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated

LTE, long-term extension; MRI, magnetic resonance imaging.

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 additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

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Step 2b Confirm eligibility requirements for LEQEMBI® coverage

Infusion considerations

Assess patient's insurance coverage. Confirm eligibility and enrollment in an AD registry if required for LEQEMBI coverage.

AD registries collect basic information, which may include:

- Site of care
- Treatment eligibility assessment
- Medical history and/or imaging

Click below to explore AD registry resources and enroll patients

ALZ-NET

CMS Registry

LEQEMBI Companion®

LEQEMBI Companion® Patient Support Program

No matter where patients are in treatment, the LEQEMBI Companion program is by their side.

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

Call 1-833-453-7362 (1-833-4-LEQEMBI). For more information about the LEQEMBI Companion program, visit LEQEMBI.com/PatientSupport

Visit LEQEMBIEnrollment.com to learn how to get patients started

AD, Alzheimer's disease; ALZ-NET, Alzheimer's Network for Treatment and Diagnostics; CMS, Centers for Medicare and Medicaid services.

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.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Step 2b

Confirm eligibility requirements for LEQEMBI® coverage (cont'd)



Obtaining access for patients starting treatment with LEQEMBI IQLIK®

After submitting a prescription directly to the specialty pharmacy, a benefits verification will determine if:

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

The specialty pharmacy will then submit the medical exception or prior authorization.

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

Medicare prescription plan[35]

The maximum out-of-pocket amount

In 2026, the maximum patient out-of-pocket cost for covered Medicare Part D drugs is $2,100. 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 and for 2027 this has been set to $2,400

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
WARNINGS AND PRECAUTIONS (cont'd)
AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)
Risk Factors of ARIA and ICH (cont'd)
Radiographic Findings of CAA (cont'd)

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.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

LEQEMBI® (lecanemab-irmb)

Step 3a Initiate treatment and monitor[31]

Initiation: First 18 Months[31]



Once-weekly LEQEMBI IQLIK®

500 mg—**two 250 mg single-dose, prefilled autoinjectors**, administered sequentially

Maintenance: Consider After 18 Months[31]



Once-weekly LEQEMBI IQLIK

360 mg—**one single-dose, prefilled autoinjector**

LEQEMBI® is also available via infusion[31]

Infusion once every 2 weeks for the first 18 months

Twice-monthly infusions — recommended starting dosage is 10 mg/kg over approximately 1 hour

Infusion once every 4 weeks after 18 months

You may give patients the option to transition to **once-monthly** infusion

- For information on switching or transitioning between LEQEMBI IQLIK and infusion administration, refer to the full Prescribing Information
- **Obtain a recent baseline brain MRI prior to initiating treatment and after months 1, 2, 3, and 6 of treatment.** In general, the MRI should be performed within approximately one week before the next scheduled infusion or injection of LEQEMBI and reviewed prior to proceeding with the infusion or injection. MRI timing is the same for both LEQEMBI IQLIK and infusion, but corresponds to different dose numbers due to route-specific dosing cadence (eg, prior to the *3rd* dose for the intravenous route or *5th* dose for the subcutaneous route)[31]
- Throughout treatment, if a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated[31]

Determine patient's infusion dose with the LEQEMBI Dosing Calculator

MRI, magnetic resonance imaging.

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 (cont'd)

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.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Step 3a Initiate treatment and monitor[31] (cont'd)

The first and only anti-amyloid treatment approved for subcutaneous initiation[31]



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

Convenient*	Proven	Easy to use
Self-injection administered at home or on the go†: Prefilled autoinjectors[31]	**Comparable efficacy and safety to the infusion regimen‡[31]**	**93%** **of early AD patients and care partners found the device easy to use§[36]**

- For detailed information on how to **prepare**, **inject in 15 seconds** (per autoinjector), and safely **dispose** of LEQEMBI IQLIK, review and advise the patient or care partner to read the FDA-approved patient labeling (Medication Guide and Instructions for Use)[31]
- LEQEMBI IQLIK may be administered by a patient or care partner after the HCP provides guidance and supervision for at least 2 consecutive subcutaneous doses and determines that administration of LEQEMBI IQLIK by the patient or care partner is appropriate[31]
- Continue to periodically reassess the appropriateness for subcutaneous treatment[31]
- Monitor for signs and symptoms of injection site reactions:
  - The safety profile of subcutaneous LEQEMBI® was similar to intravenous infusion. Subcutaneous dosing was associated with mostly localized and less frequent systemic injection-related reactions, majority at first dose when initiating therapy[31]
- After 18 months, patients may transition to 360 mg once-weekly (one single-dose prefilled autoinjector)[31]

***In comparison with the administration of LEQEMBI infusion.**[31]

†For detailed information on storage and handling of LEQEMBI IQLIK, see the full Prescribing Information, including Instructions for Use.

‡The effectiveness of subcutaneous LEQEMBI is based on the established effectiveness of LEQEMBI infusion, supported by comparable pharmacokinetic exposures and reductions of amyloid beta plaque level.[31]

§Based on in-person interviews of 50 patients with early AD and 50 care partners currently assisting people with early AD. Participants were given the opportunity to interact with a training autoinjector device (containing no needles or medication) and an injection pad, then asked to answer computer-based surveys about their experience, including "How difficult or easy was it to use the self-injection device?"[36]

AD, Alzheimer's disease; HCP, health care provider.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

LEQEMBI® (lecanemab-irmb)

Step 3a Initiate treatment and monitor[31] (cont'd)

If starting on LEQEMBI IQLIK®

Prescribe LEQEMBI IQLIK by sending your patient's prescription directly to the specialty pharmacy

For detailed information on how to prepare, inject in 15 seconds (per autoinjector), and dispose of LEQEMBI IQLIK, review and advise the patient and/or care partner to read the FDA-approved prescribing information, with Medication Guide and Instructions for Use.

- Sites for injection include the abdomen or upper thigh. The back of the upper arm can also be used as an injection site if healthcare provider or caregiver administers the injection
- Do not inject into moles, scars, bruises, tattoos, or into areas where the skin is red, hard, tender, or injured

Things to consider:

- Provide clinical oversight throughout treatment
- You and your staff should provide the specialty pharmacy with any clinical preferences with respect to the specialty pharmacy process
- 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

For patients who obtain LEQEMBI IQLIK from the LEQEMBI® Specialty Pharmacy Network*

CareMed and Walgreens provide support with:

- Prescription fulfillment, including prior authorization (PA) support, financial assistance navigation, and LEQEMBI Companion® coordination
- Patient onboarding and ongoing shipment coordination calls, and distribution of sharps containers
- MRI adherence reminders to prescribing physician's office

In addition, Eisai has contracted CareMed and Walgreens to provide the following non-clinical support for patients:

- Shipment of a LEQEMBI Welcome Kit, including a demonstration device and educational resources designed to set clear expectations for starting and continuing LEQEMBI IQLIK
- For patients who opt-in, ongoing clinical education during the first 6 months of LEQEMBI IQLIK treatment to support adherence, answer questions, and reinforce treatment expectations

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)

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)

*LEQEMBI IQLIK may also be obtained from specialty pharmacies that are not part of the LEQEMBI Specialty Pharmacy Network.

MRI, magnetic resonance imaging.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

Step 3a Initiate treatment and monitor[31] (cont'd)

If starting on LEQEMBI® infusion

Coordinate with infusion staff for a smooth start to treatment[31]

For detailed information on how to prepare and administer LEQEMBI for infusion, review the Prescribing Information and advise the patient or care partner to read the FDA-approved patient labeling (Medication Guide)

- Visually inspect the LEQEMBI diluted solution for particles or discoloration prior to administration. Do not use if it is discolored, or opaque, or if foreign particles are seen
- Prior to infusion, allow the LEQEMBI diluted solution to warm to room temperature
- Infuse the entire volume of LEQEMBI diluted solution intravenously over approximately 1 hour through an IV line containing a terminal low–protein binding 0.2 micron in-line filter. Flush infusion line to ensure all LEQEMBI is administered
- Monitor for any signs or symptoms of an infusion-related reaction. The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider premedication at subsequent dosing with antihistamines, nonsteroidal anti-inflammatory drugs, or corticosteroids. See Infusion-Related Reactions Warnings and Precautions
- If a starting dosage or maintenance dosage infusion is missed, administer the next dose as soon as possible

Follow-up infusions[31]

- After each infusion, ensure the patient/care partner has confirmed an appointment for their next infusion in 2 to 4 weeks, depending on whether they are in initiation or maintenance phase
- **Respond promptly to any inbound requests from infusion sites; they may need specific paperwork to confirm patient eligibility and ensure reimbursement**
- Ensure regular follow-up with patients to monitor compliance and address any questions

To identify an infusion site near your practice, visit **LeqembiLocator.com**

IV, intravenous.

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 (cont'd)

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.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

LEQEMBI® (lecanemab-irmb)

Step 3b

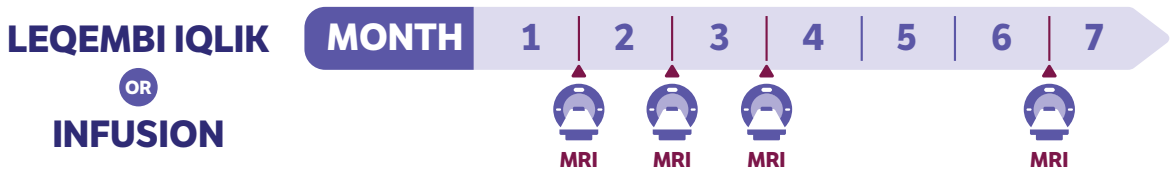
Perform follow-up MRIs to monitor for ARIA[31]

Proactively coordinate MRI schedules with the care team to ensure all scans are completed prior to treatment administration

- Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI®[31]

MRI timing is the same for both LEQEMBI IQLIK® and Infusion[31]

Obtain a recent baseline brain MRI prior to initiating treatment and after months 1, 2, 3, and 6 of treatment.



- **Obtain an MRI after months 1, 2, 3, and 6 of treatment (eg, prior to the *3rd* dose for the intravenous route or *5th* dose for the subcutaneous route)**
  - In general, the MRI should be performed within approximately one week before the next scheduled 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
  - Confirm the next appointment and discuss any possible obstacles or barriers to care

Steps to consider

- 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

Operational considerations by route:

INFUSION

- Coordinate MRI timing in relation to scheduled infusion visits
- Communicate proactively with infusion centers and neuroradiology to align appointments
- Build in buffer time to help avoid infusion delays if MRI results are pending

LEQEMBI IQLIK

- Consider scheduling MRIs up front based on uninterrupted treatment milestones
- Communicate proactively with neuroradiology to align appointments

ARIA, amyloid-related imaging abnormalities; MRI, magnetic resonance imaging.

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 (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.

Please see additional Select Safety Information throughout.
Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

If ARIA is present, know the recommendations and be prepared to adjust the patient's dosing schedule[31]

› Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity[31]

ARIA-E severity on MRI[31]			
Clinical symptom severity*	**Mild**	**Moderate**	**Severe**
Asymptomatic	**May continue dosing**	Suspend dosing†	Suspend dosing†
Mild	**May continue dosing based on clinical judgment**		
Moderate or severe	Suspend dosing†		

ARIA-H severity on MRI[31]			
Clinical symptom severity	**Mild**	**Moderate**	**Severe**
Asymptomatic	**May continue dosing**	Suspend dosing‡	Suspend dosing§
Symptomatic	Suspend dosing‡		

*Mild: Discomfort noticed, but no disruption of normal daily activity. Moderate: Discomfort sufficient to reduce or affect normal daily activity. Severe: Incapacitating, with inability to work or to perform normal daily activity.
† Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.
‡ Mild/moderate: Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.
§ Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; use clinical judgment in considering whether to continue treatment or permanently discontinue LEQEMBI®.

If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment. Dosing was able to be continued in most patients with ARIA[31]

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

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

LEQEMBI® (lecanemab-irmb)

Step 3c

Connect with key stakeholders to help patients start and stay on treatment

As you navigate LEQEMBI® treatment, consider implementing these steps in your practice:

- Perform baseline MRI and consider conducting subsequent MRIs with the same imaging center[31]
- Perform functional and cognitive assessments to confirm current disease stage[1]
- Confirm Aβ pathology with PET, CSF, or BBMs[20,32]
- Recommend testing for ApoE ε4 to identify patients at elevated risk of ARIA[31]
- Request that neuroradiologist documents the presence or absence of ARIA in the EMR
- Communicate clearly with patient or care partners to help them feel invested in their care
- Give neuroradiology adequate evaluation time when scheduling each MRI
- Coordinate with infusion sites about any safety concerns
- Communicate with infusion sites on potential changes to dosing administration

Aβ, amyloid beta; ApoE ε4, Apolipoprotein E ε4; ARIA, amyloid-related imaging abnormalities; BBM, blood-based biomarker; CSF, cerebrospinal fluid; EMR, electronic medical record; MRI, magnetic resonance imaging; PET, positron emission tomography.

Please see additional Select Safety Information throughout.
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 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

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

LEQEMBI®
(lecanemab-irmb)

Discover how to intervene early for patients with MCI due to AD or mild AD dementia[1,29]

Visit **Leqembihcp.com** to learn more

SUMMARY OF WARNINGS & PRECAUTIONS:

- Amyloid-Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E ε4 homozygotes compared to heterozygotes and noncarriers. The risk of ARIA-E and ARIA-H is increased in patients with pretreatment microhemorrhages and/or superficial siderosis. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning if indicated.
- Infusion-Related Reactions: The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider pre-medication at subsequent dosing with antihistamines, nonsteroidal anti-inflammatory drugs, or corticosteroids

AD, Alzheimer's disease; ARIA, amyloid-related imaging abnormalities; ARIA-E, amyloid-related imaging abnormalities-edema; ARIA-H, amyloid-related imaging abnormalities-hemosiderin deposition; MCI, mild cognitive impairment; MRI, magnetic resonance imaging.

Please see additional Select Safety Information throughout. Please see full Prescribing Information for LEQEMBI, including Boxed WARNING.

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