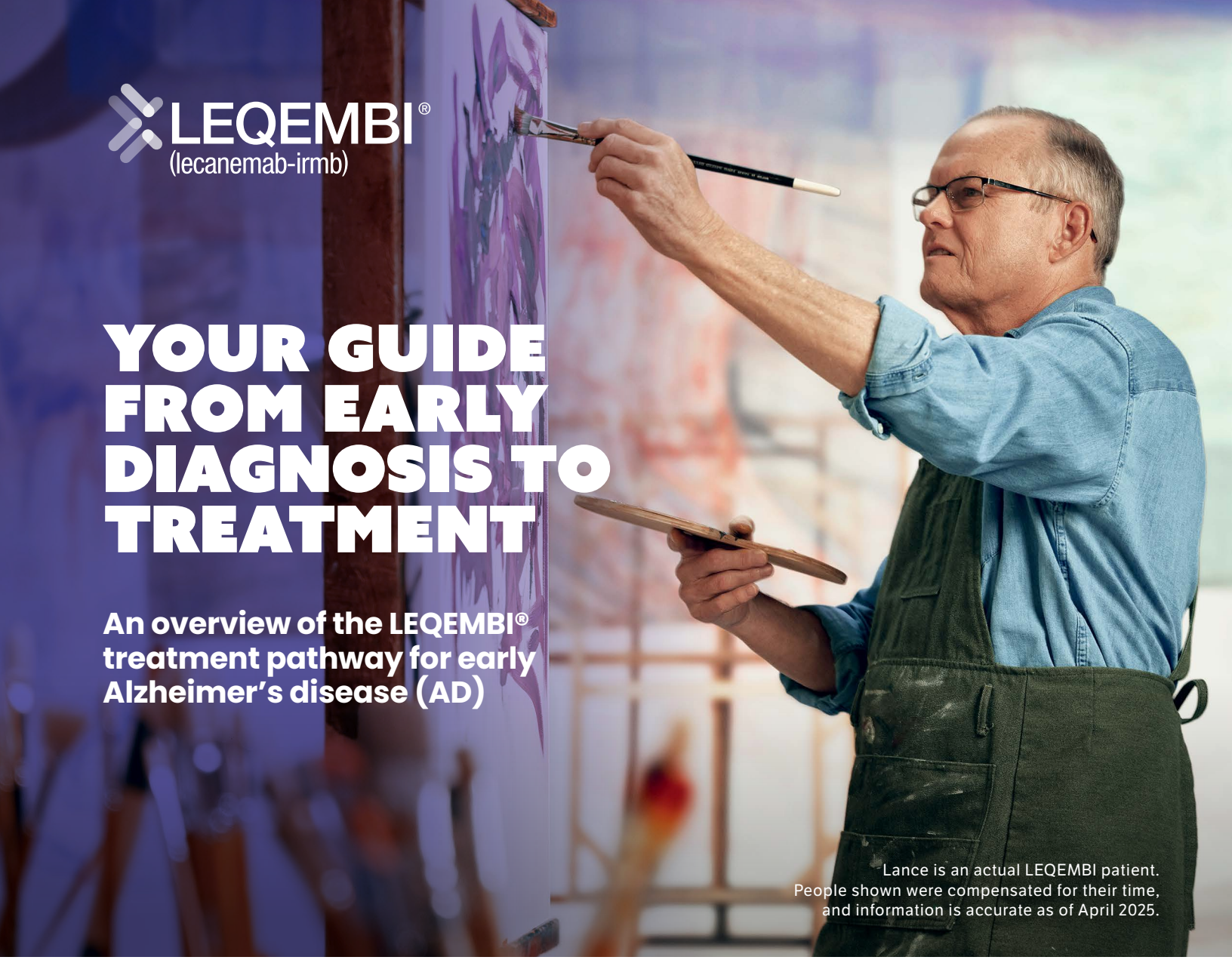
LEQEMBI®
(lecanemab-irmb)

YOUR GUIDE FROM EARLY DIAGNOSIS TO TREATMENT

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



Lance is an actual LEQEMBI patient.
People shown were compensated for their time,
and 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 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

Lance is an actual LEQEMBI patient and Liz is his care partner. People shown were compensated for their time, and information is accurate as of April 2025.

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.

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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 of disease 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 stages of AD depicted above in equal size are not necessarily equal in duration.

The earlier MCI due to AD and mild AD dementia are diagnosed and treated, the greater the opportunity for benefit.[2,3]

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

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Step 1

Assess patient eligibility and readiness for LEQEMBI®

Proactive steps to diagnose AD at the earliest symptomatic stages

✔ CHECK FOR COGNITIVE IMPAIRMENT[4-7]

- 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 used to identify daily activity such as: FAQs, FAST, CDR-SB
- Many neurocognitive tests are available to aid in the diagnosis of dementia or dementia due to AD, but not every test has the sensitivity to assess a patient with MCI

Consider using MCI due to AD–sensitive and/or mild AD dementia–sensitive cognitive assessments to identify early stages of AD

- Cognitive assessments available such as: **MoCA, SLUMS, AD8, and Mini-Cog©**

✔ RULE OUT NON-AD CAUSES[4,8,9]

- 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 MRI can rule out other causes** such as tumors, evidence of strokes, damage from severe head trauma, or a build-up of fluid in the brain

✔ CONFIRM AD DIAGNOSIS[10-12]

- A biomarker-confirmed AD diagnosis allows for the identification of patients appropriate for amyloid beta (Aβ)-targeting therapy, like LEQEMBI
- **Options for performing Aβ confirmation include amyloid PET scans, CSF, and FDA-cleared and other commercially available blood-based biomarkers (BBMs)**

AD, Alzheimer's disease; AD8, Eight-item Informant Interview to Differentiate Aging and Dementia; BBM, blood-based biomarkers; CDR-SB, Clinical Dementia Rating-Sum of Boxes; CSF, cerebrospinal fluid; CT, computed tomography; FAQ, Functional Activities Questionnaire; FAST, Functional Assessment Staging Tool; FDA, US Food and Drug Administration; MoCA, Montreal Cognitive Assessment; MRI, magnetic resonance imaging; PET, positron emission tomography; 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.

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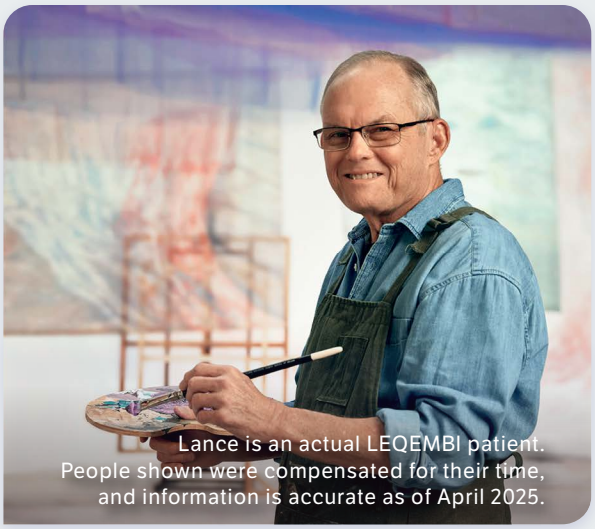
Assess patient eligibility and readiness for LEQEMBI®

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 and availability for repeated infusions and 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 infusion schedules



Lance is an actual LEQEMBI patient. People shown were compensated for their time, and information is accurate as of April 2025.

As you talk with patients about starting LEQEMBI, discuss the additional maintenance dosing options they'll have after completing 18 months of treatment[2]

Initiation period (first 18 months): Patients will receive twice-monthly infusions (once every 2 weeks).[2]

Maintenance period (after 18 months): Patients may transition to once-monthly infusions (once every 4 weeks) or once-weekly at-home subcutaneous injections with **LEQEMBI IQLIK**. At the discretion of the physician, patients may also continue receiving twice-monthly infusions.[2]

Things to consider when deciding on a maintenance option for your patient:

Clinical considerations before transitioning to maintenance dosing[2]:

- Patient has completed 18 months of **LEQEMBI** infusion initiation therapy and is clinically stable based on clinician assessment (or judgment)

Transition to LEQEMBI IQLIK if patient:

- Feels comfortable self-injecting or has a designated care partner who can support at-home injections
- Travels while still staying on schedule*

Stay on infusion if patient:

- Benefits from the community aspect of infusion site

*Once the autoinjector has come to room temperature (77° F/25° C) it should be maintained at that temperature in the original carton for up to 14 days. It cannot go back into the refrigerator.

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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.[2]

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

ARIA-E[2]

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

ARIA-H[2]

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[2]

- 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[2]
- Clinical symptoms associated with ARIA resolved in 79% (23/29) of patients during the period of observation[2]
- ARIA-H that occurred with ARIA-E tended to occur early (within 6 months)[13]
- Serious events of ARIA occurred in 3% of ApoE ε4 homozygotes and in ~1% of the heterozygotes and noncarriers[2]

Incidence of ARIA[2,3]

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.[2]

ARIA-E: ARIA with edema can be observed on MRI as brain edema or sulcal effusions.[2]

ARIA-H: ARIA with hemosiderin deposition includes microhemorrhage and superficial siderosis.[2]

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.

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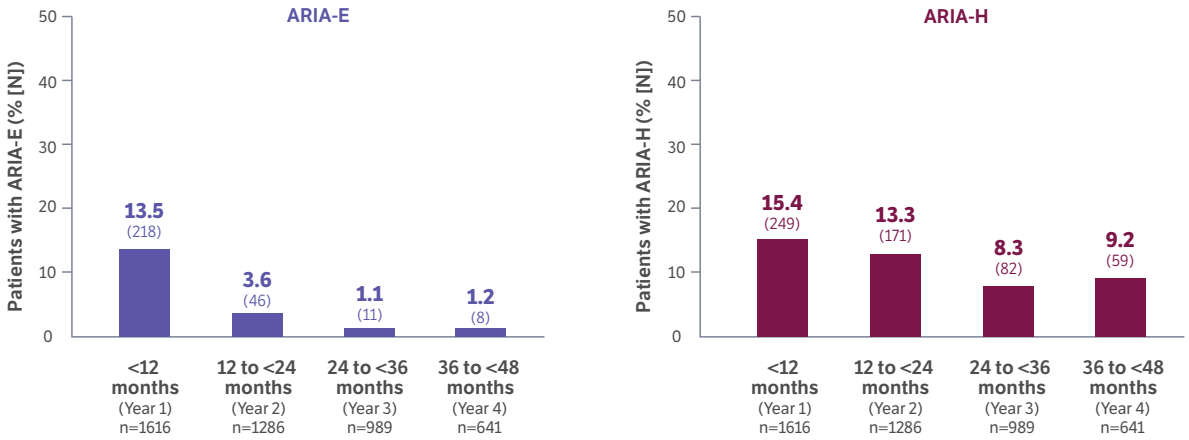
The incidence of ARIA decreased after 12 months as patients continued therapy with LEQEMBI®[14]

Clarity AD Core period and LTE: Rates of ARIA-E and ARIA-H by years*[14]



*Infusion only data.[14]
Cutoff: March 31, 2025.[14]
The LTE study is ongoing.[15]

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

- A baseline MRI is required to initiate LEQEMBI therapy as well as 4 MRIs, each prior to the 3rd, 5th, 7th, and 14th infusions to monitor for ARIA[2]
- ApoE ε4 testing is recommended to establish ARIA risk but is not required[2,16]
- Throughout treatment, if a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated[2]

LTE, long-term extension.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)

Incidence of ARIA

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. 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.

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Step 2b

Confirm eligibility and enrollment in an AD registry if required for LEQEMBI® coverage

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

Scan below to explore AD registry resources and enroll patients

ALZ-NET

CMS Registry

LEQEMBI Companion™

LEQEMBI Companion is by their side

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

As a part of the LEQEMBI Companion program, Eisai Patient Support (EPS) offers information and resources for accessing LEQEMBI for eligible patients. Once enrolled in the LEQEMBI Companion Program, patients will be connected with a dedicated Patient Navigator, who can help them understand insurance coverage, identify financial support, find infusion centers, and know what to expect at each step.

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 & Medicaid Services.

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.

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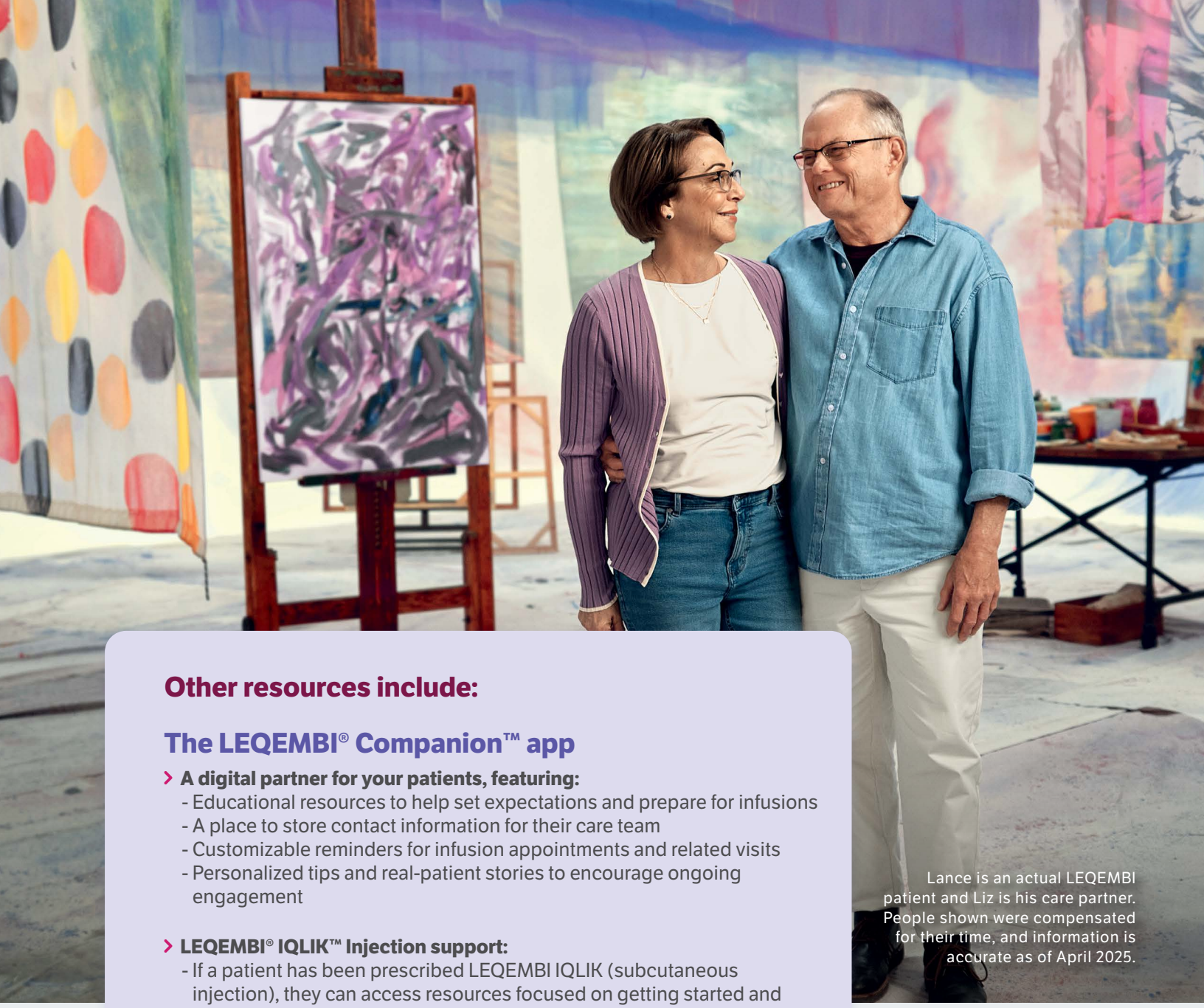

Other resources include:

The LEQEMBI® Companion™ app

- **A digital partner for your patients, featuring:**
  - Educational resources to help set expectations and prepare for infusions
  - A place to store contact information for their care team
  - Customizable reminders for infusion appointments and related visits
  - Personalized tips and real-patient stories to encourage ongoing engagement

- **LEQEMBI® IQLIK™ Injection support:**
  - If a patient has been prescribed LEQEMBI IQLIK (subcutaneous injection), they can access resources focused on getting started and staying on track with their treatment schedule

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SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)

Risk Factors of ARIA and ICH

ApoE ε4 Carrier Status

Of the patients taking LEQEMBI, 16% were ApoE ε4 homozygotes, 53% were heterozygotes, and 31% were noncarriers. With LEQEMBI, ARIA was higher in ApoE ε4 homozygotes (LEQEMBI: 45%; placebo: 22%) than in heterozygotes (LEQEMBI: 19%; placebo: 9%) and noncarriers (LEQEMBI: 13%; placebo: 4%). Symptomatic ARIA-E occurred in 9% of ApoE ε4 homozygotes vs 2% of heterozygotes and 1% of noncarriers. Serious ARIA events occurred in 3% of ApoE ε4 homozygotes and in ~1% of heterozygotes and noncarriers. The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers.

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LEQEMBI®
(lecanemab-irmb)

Step 3a Initiate treatment and monitor

Only LEQEMBI® empowers patients with maintenance dosing options to help them continue their treatment journey[2,17]

A baseline MRI is required to initiate treatment.[2]

Initiation period[2]

First 18 months

Twice-monthly infusion
(once every 2 weeks)

&

Four MRIs: Each prior to the 3rd, 5th, 7th, and 14th infusions to monitor for ARIA[1]

MRI should be performed within approximately 1 week before the scheduled infusion of LEQEMBI and reviewed prior to proceeding with the infusion.[2]

Only LEQEMBI offers titration-free dosing from the start—the recommended starting dosage is 10 mg/kg infusion over approximately 1 hour, twice monthly[2,17]

Throughout treatment, if a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.[2]

Maintenance period[2]

After 18 months

Once-monthly infusion*
(once every 4 weeks)

or

LEQEMBI® IQLIK™

Once-weekly at-home subcutaneous injection
360 mg/1.8 mL (200 mg/mL)

*10 mg/kg once every 4 weeks. Patients may also continue with 10 mg/kg twice-monthly infusion dosing after 18 months.[2]

Patients who continue on therapy beyond 18 months may be able to maintain treatment benefits for longer[2]

- **No amyloid level testing is required to transition to maintenance therapy[2]**
- No additional MRIs are required, unless symptoms are experienced[2]
- Duration of therapy is up to the discretion of the HCP and patient[2]
- If transitioning from starting dosage to a maintenance dosage regimen, administer the first maintenance dose 2 weeks after the last starting dose[2]

At 12-month appointment

Discuss the maintenance treatment options with your patients and assess their level of interest in either **continuing with infusion treatment (twice-monthly [once every 2 weeks] or once-monthly maintenance) or switching to the subcutaneous injection at 18 months.**[2]

Take the opportunity to:

- Identify whether the patient is appropriate for and motivated to continue therapy
- Assess which long-term maintenance dose formulation is appropriate to use
- Schedule their next follow-up appointment

AD, Alzheimer's disease; ARIA, amyloid-related imaging abnormalities; HCP, health care professional; IV, intravenous; MRI, magnetic resonance imaging; SC, subcutaneous.

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.

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LEQEMBI®
(lecanemab-irmb)

Initiate treatment and monitor

The first and only anti-amyloid therapy to offer at-home injection to help patients continue their treatment journey after 18 months[2,16]

- **Once-weekly** at-home subcutaneous administration[2]
- **Prepare, inject in 15 seconds, and dispose**[2]
- **Single-dose prefilled autoinjector:** 360 mg/1.8 mL (200 mg/mL)[2]
- For detailed information on how to prepare, administer, and safely dispose of LEQEMBI IQLIK, review and advise the patient and/or care partner to read the FDA-approved patient labeling (Medication Guide and Instructions for Use)
- During maintenance dosing, patients may switch from infusion (once every 4 weeks) to subcutaneous LEQEMBI IQLIK (once weekly), or vice versa. Initiate this transition at 1 week after the last maintenance dose[2]
- Monitor for signs and symptoms of an injection reaction[2]

Consider which patients are appropriate candidates for LEQEMBI® IQLIK™:

- Feel comfortable using an autoinjector, or have a designated care partner who can support once-weekly at-home injections
- Travel while still staying on schedule*

*Once the autoinjector has come to room temperature (77 °F/25 °C), it should be maintained at that temperature. It cannot go back into the refrigerator.[2]

When to start transition based on change of dosing option[2]

Current route of administration/dosing	Updated route of administration/dosing	Transition timing
IV initiation (every 2 weeks)	IV maintenance (every 4 weeks)	Start 2 weeks after last infusion
	SC maintenance (every week)	
IV maintenance (every 4 weeks)	SC maintenance (every week)	Start 1 week after last infusion
SC maintenance (every week)	IV maintenance (every 4 weeks)	Start 1 week after last injection

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LEQEMBI® (lecanemab-irmb)

Step 3b Coordinate with infusion site staff to ensure starting IV treatment is smooth

Preparing patients for infusion[2]

1 **Calculate the dose (mg), the total volume (mL) of LEQEMBI® solution required, and the number of vials needed** based on the patient's actual body weight and recommended dose of 10 mg/kg. Each vial contains a LEQEMBI concentration of 100 mg/mL[2]

Determine patient's dose with the LEQEMBI Dosing Calculator

2 **Prior to administration, LEQEMBI must be diluted in 250 mL of 0.9% Sodium Chloride Injection, USP**[2]

- Consider checking the medical record for any weight changes prior to each infusion

Initiate and maintain treatment with LEQEMBI and monitor for safety

Dilution[2]

- Each mL of solution contains 100 mg of lecanemab-irmb and arginine hydrochloride (42.13 mg), histidine (0.18 mg), histidine hydrochloride monohydrate (4.99 mg), polysorbate 80 (0.50 mg), and water for injection at an approximate pH of 5.0
- Before every infusion, calculate the dose (mg), the total volume (mL) of LEQEMBI solution required, and the number of vials needed based on the patient's actual body weight and the recommended dose of 10 mg/kg
- Use aseptic technique when preparing the LEQEMBI diluted solution for infusion
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Check that the LEQEMBI solution is clear to opalescent and colorless to pale yellow. Do not use if opaque particles, discoloration, or other foreign particles are present
- Remove the flip-off cap from the vial. Insert the sterile syringe needle into the vial through the center of the rubber stopper
- Withdraw the required volume of LEQEMBI from the vial(s) and add to an infusion bag containing 250 mL of 0.9% Sodium Chloride Injection, USP
- Each vial is for one-time use only. Discard any unused portion
- Gently invert the infusion bag containing the LEQEMBI diluted solution to mix completely. Do not shake
- After dilution, immediate use is recommended. If not administered immediately, store LEQEMBI refrigerated at 2°C to 8°C (36°F to 46°F) for up to 4 hours, or at room temperature up to 30°C (86°F) for up to 4 hours. Do not freeze

IV, intravenous.

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LEQEMBI® (lecanemab-irmb)

Coordinate with infusion site staff to ensure starting IV treatment is smooth

Administration[2]

- Visually inspect the diluted LEQEMBI® solution for particles or discoloration prior to administration. Do not use if it is discolored, or opaque, or foreign particles are seen
- Prior to infusion, allow the diluted LEQEMBI solution to warm to room temperature
- Infuse the entire volume of the diluted LEQEMBI solution intravenously for approximately 1 hour through an IV line containing a terminal low-protein binding 0.2 micron in-line filter. Flush infusion 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 pre-medication at subsequent dosing with antihistamines, nonsteroidal anti-inflammatory drugs, or corticosteroids

Follow-up infusions[2]

- After each infusion, ensure the patient/care partner has confirmed an appointment for their next infusion in 2 to 4 weeks, depending if 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 ensure compliance and address any questions

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

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.

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Step 3c

Perform follow-up MRIs to monitor for ARIA[2,18]

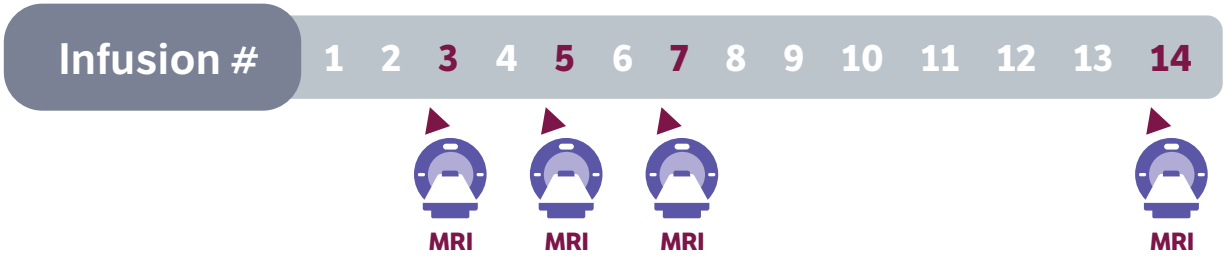
Proactively coordinate infusion and MRI schedules with infusion sites and neuroradiologists to ensure all scans are completed prior to the associated infusions[2]

- Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI®[2]

Monitoring and scheduling infusions[2]

Obtain a recent brain MRI prior to initiating therapy with LEQEMBI[1]

In general, the MRI should be performed within approximately 1 week before the scheduled infusion of LEQEMBI and reviewed prior to proceeding with the infusion



- If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated[2]
- In clinical trials, monitoring MRIs were scheduled after patients tolerated the first dose well[2]
- 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

If ARIA is observed on MRI[2,18]

- Careful clinical evaluation should be performed prior to continuing treatment
- Confirm the next appointment and discuss any possible obstacles or barriers to care

SELECT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (cont'd)
AMYLOID-RELATED IMAGING ABNORMALITIES (cont'd)
Risk Factors of ARIA and ICH (cont'd)
Concomitant Antithrombotic or Thrombolytic Medication

In Clarity AD, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed if the patient was on a stable dose. Most exposures were to aspirin. Antithrombotic medications did not increase the risk of ARIA with LEQEMBI. The incidence of ICH: 0.9% in patients taking LEQEMBI with a concomitant antithrombotic medication vs 0.6% with no antithrombotic and 2.5% in patients taking LEQEMBI with an anticoagulant alone or with antiplatelet medication such as aspirin vs none in patients receiving placebo.

Fatal cerebral hemorrhage has occurred in 1 patient taking an anti-amyloid monoclonal antibody in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent.

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If ARIA is present, know the recommendations and be prepared to adjust the patient's infusion schedule[2,18]

ARIA-E severity on MRI[2]			
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[2]			
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.

- In patients who suspend dosing due to ARIA, consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification[2]
- Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity[2]

Throughout treatment, if a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated[2]

ARIA, amyloid-related imaging abnormalities; ARIA-E, amyloid-related imaging abnormalities-edema; ARIA-H, amyloid-related imaging abnormalities-hemosiderin deposition; 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 3d

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[2]
- Perform functional and cognitive assessments to confirm current disease stage[1]
- Confirm Aβ pathology with PET, CSF, or blood-based biomarkers (BBMs)
- Recommend testing for ApoE ε4 to identify patients at elevated risk of ARIA[2]
- Request that neuroradiologist documents the presence or absence of ARIA in the EMR
- Communicate clearly with patient and/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 after 18 months on therapy[2]

ApoE ε4, apolipoprotein E ε4; ARIA, amyloid-related imaging abnormalities; CSF, cerebrospinal fluid; EMR, electronic medical record; MRI, magnetic resonance imaging; PET, positron emission tomography.

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)

Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI®. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with LEQEMBI.

Caution should be exercised when considering the use of LEQEMBI in patients with factors that indicate an increased risk for ICH and, in particular, patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

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LEQEMBI® (lecanemab-irmb)

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%)
- Safety profile of LEQEMBI IQLIK for maintenance treatment was similar to LEQEMBI infusion. Patients who received LEQEMBI IQLIK experienced localized and systemic (less frequent) injection-related reactions (mild to moderate in severity)

LEQEMBI (lecanemab-irmb) is available:

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

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LEQEMBI®
(lecanemab-irmb)

Discover how to intervene early for patients with MCI due to AD or mild AD dementia[2,3]

Visit **Leqembihcp.com** to learn more

Lance is an actual LEQEMBI patient.
People shown were compensated for their time, and information is accurate as of April 2025.

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, non-steroidal anti-inflammatory drugs, or corticosteroids

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

Please see additional Select Safety Information throughout.
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