MADISON NEUROLOGY LLC

608 403 0000

Neurology Care 7 days a Week. Because Your Brain Matters.

Leqembi®

Lecanemab-irmb

COMPLETE CLINICAL PROTOCOL: PRE-TREATMENT CHECKLIST • ORDER SET • FOLLOW-UP • HOLD/DISCONTINUE CRITERIA

GENERIC NAME	lecanemab-irmb
BRAND	LEQEMBI®
MEDICATION CLASS	Anti-amyloid beta monoclonal antibody
PRESENTATION	500 mg/5 mL and 200 mg/2 mL (100 mg/mL) single-dose vials — dilute in 250 mL 0.9% NaCl
ROUTE	IV infusion over approximately 1 hour, every 2 weeks
US INDICATION (FDA)	Alzheimer's disease — treatment should be initiated in patients with MILD cognitive impairment or mild dementia stage of disease (the population studied), with confirmed amyloid beta pathology.

Class context.
Boxed warning: ARIA (amyloid-related imaging abnormalities) — edema (ARIA-E) and hemorrhage (ARIA-H). Usually asymptomatic and MRI-detected, but serious and fatal events have occurred. Risk is highest early in treatment and markedly elevated in APOE ε4 homozygotes; fatal intracerebral hemorrhage has occurred with thrombolytics in anti-amyloid–treated patients.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ Confirm amyloid beta pathology BEFORE initiation: amyloid PET, or CSF/plasma biomarker per the label pathway. Dosing without confirmed amyloid is not indicated.

☐ Baseline brain MRI (within 1 year before starting) — REQUIRED. Exclude: pre-existing ARIA-E, superficial siderosis, more than 4 microhemorrhages, any hemorrhage >1 cm, vasogenic edema, severe white-matter disease, or other exclusionary findings.

- ☐ APOE ε4 genotyping — encouraged before treatment to inform risk counseling; homozygotes have substantially higher ARIA rates. Document shared decision-making either way (testing is a choice, not a mandate).
- ☐ Cognitive staging (MoCA/MMSE, CDR with caregiver) — confirm MCI or mild dementia; treatment is not indicated in moderate/severe disease.
- ☐ Medication review: ANTICOAGULANTS and any thrombolytic-eligibility profile — document the hemorrhage risk-benefit discussion explicitly.
- ☐ Pregnancy test when relevant.

B. Vaccinations

- ☐ No label restrictions; update routine adult vaccines per primary-care guidance.

C. Clinical assessments & counseling

- ☐ Baseline cognitive and functional assessment WITH a caregiver present — caregiver report is the early-warning system for ARIA symptoms.
- ☐ ARIA education for patient AND caregiver: headache, confusion, dizziness, visual change, nausea, gait difficulty → call before the next dose; some ARIA is asymptomatic and MRI-only, which is why the scan schedule is mandatory.
- ☐ Confirm the center's urgent-MRI pathway and after-hours contact plan BEFORE the first dose.
- ☐ Stroke-alert plan: families and local EMS/ED contacts should know the patient is on an anti-amyloid antibody — thrombolysis decisions are materially different.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
No confirmed amyloid pathology	Do not start.
Exclusionary baseline MRI (ARIA-E, siderosis, >4 microhemorrhages, hemorrhage >1 cm, vasogenic edema)	Do not start; the pretreatment MRI is a gate, not a formality.
Moderate or severe dementia	Outside the studied/labeled population.
Anticoagulation or high thrombolysis likelihood without specialist review	Hold initiation pending explicit risk-benefit documentation.

Section 2 — Order Set

Premedication

- ☐ None required by label. After a mild-moderate infusion reaction, subsequent infusions may be premedicated with antihistamine ± antipyretic ± corticosteroid.

Dosing schedule

Standard dose	10 mg/kg IV over approximately 1 hour, every 2 weeks.

Infusion reactions	Interrupt or slow for reactions; manage by severity; consider premedication for subsequent doses after a reaction.
Observation	Observe during and after infusion per institutional protocol; first exposures warrant the closest observation.

Standing orders — every infusion

- ☐ ARIA symptom review (patient + caregiver) before EVERY dose.
- ☐ Verify surveillance MRI completion before doses 5, 7, and 14 — do not infuse blind past an overdue MRI.
- ☐ Weight check periodically (weight-based dosing); medication review each cycle (new anticoagulants/antiplatelets).

Missed or delayed dose

Administer a missed dose as soon as possible and resume the every-2-week schedule from that date.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Brain MRI (ARIA surveillance)	Before the 5th, 7th, and 14th infusions per label; additional MRI immediately for ANY ARIA symptom; enhanced surveillance for APOE ε4 carriers per current label	ARIA on MRI → apply the label's severity-based hold/resume algorithm; moderate–severe or symptomatic ARIA suspends dosing until resolution.
ARIA symptom review	Before every infusion, caregiver corroborated	Any new symptom → MRI before the next dose.
Cognitive/functional assessment	Every 6–12 months	Documents trajectory and continuation rationale.
Medication review (anticoagulant/antiplatelet)	Every cycle	New anticoagulation → hold and re-evaluate risk.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
ARIA on surveillance MRI	Hold per the label algorithm: asymptomatic mild ARIA may continue with intensified monitoring; moderate–severe or symptomatic ARIA suspends dosing until MRI resolution.
Any new neurologic symptom	MRI before the next dose.
New anticoagulation or anticipated thrombolysis	Hold; specialist re-evaluation.
Planned surgery/procedures with bleeding risk	Coordinate timing with the prescriber.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Serious or recurrent symptomatic ARIA; ARIA with significant hemorrhage	Discontinue.
Intracerebral hemorrhage >1 cm or recurrent imaging instability	Discontinue.
Progression beyond the mild disease stage	Reassess benefit — continuation beyond the studied population is individualized.
Anaphylaxis/serious hypersensitivity	Discontinue.

Section 5 — Notes & Practical Points

- ☐ The every-2-week cadence plus MRI gating makes adherence logistics the main operational challenge — build MRI scheduling into the infusion calendar from day one.
- ☐ Document the APOE discussion even when the patient declines testing; payers and guidelines increasingly expect it.

Prepared November 2026 by Madison Neurology LLC.

This document is an educational compilation and does not reproduce the complete prescribing information. Verify every element against the current FDA label and applicable REMS requirements before clinical use.

- Current U.S. prescribing information via NIH DailyMed — https://dailymed.nlm.nih.gov/dailymed/
- FDA Drugs@FDA database — https://www.accessdata.fda.gov/scripts/cder/daf/
- FDA drug safety and availability updates — https://www.fda.gov/drugs/drug-safety-and-availability

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Questions about infusion referrals: call 608 403 0000. Neurology Care 7 days a Week. Because Your Brain Matters.