

LECANEMAB-IRMB (LEQEMBI™) MEDICAL POLICY ¹

POLICY NUMBER:

EFFECTIVE DATE: [MM/DD/YYYY]

DEVELOPED BY: [Employee Name]

LAST UPDATED: [MM/DD/YYYY]

APPROVED BY: [Employee Name]

POLICY:

Lecanemab is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease. This facility is committed to providing high-quality care, promoting patient safety, and supporting staff adherence to best practices. This policy, in conjunction with relevant departmental policies, establishes a standardized process for the safe administration of lecanemab.

SCOPE:

This policy applies to all personnel at [facility] who are responsible for the preparation and/or administration of parenteral medications.

RESPONSIBILITIES:

It is the responsibility of [insert title of the responsible party] to ensure that all personnel responsible for the preparation and administration of parenteral medications complete the required education and training according to [insert facility policy on staff training and education].

It is the responsibility of every personnel responsible for the preparation and administration of parenteral medication to adhere to the contents of this policy and remain current with facility training.

ACRONYMS:

Aβ	amyloid beta
ARIA	Amyloid Related Imaging Abnormalities
CSF	cerebrospinal fluid
FDA	Food and Drug Administration
MRI	magnetic resonance imaging
p-tau	phosphorylated tau
PET	positron emission tomography
t-tau	total tau
USP	United States Pharmacopeia
VAD	vascular access device

¹ The National Infusion Center Association (NICA) develops templates to be used as a reference to support, not replace, the use of professional judgment in the development of organization-specific policies. NICA templates are for informational purposes only and may not reflect all relevant regulations and requirements from applicable oversight agencies including but not limited to state/local health departments, departments of professional licensure, FDA, or other regulatory authorities. NICA assumes no responsibility for any damages or adverse effect(s) resulting from or related to the readers' interpretation or application of this information. For complete medication information, refer to www.leqembi.com

Criteria and Indications for Use:

- Lecanemab is indicated for the treatment of early Alzheimer's disease (mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease dementia, with confirmed amyloid pathology).
 - Approved diagnoses²:
 - G30.0 Alzheimer's Disease, early onset
 - G30.1 Alzheimer's Disease, late onset
 - G30.8 Other Alzheimer's disease
 - G30.9 Alzheimer's disease, unspecified
 - G31.84 Mild Cognitive Impairment, so stated
- ← G30.X codes require secondary F02.8X code →
- F02.80 Dementia without behavioral disturbance
 - F02.81 Dementia with behavioral disturbance

PROCEDURE:

1) Review Referral:

- a) Confirm order for lecanemab is complete and signed by a licensed independent practitioner with active prescriptive authority.
- b) All referrals must be accompanied by documentation supporting medical necessity, including but not limited to:
 - i) Medical records confirming cognitive impairment using a validated tool, such as:
 - (1) General Practitioner Assessment of Cognition (GPCOG), OR
 - (2) Memory Impairment Screen (MIS), OR
 - (3) Mini-Cog™, OR
 - (4) Mini-Mental State Examination (MMSE)
 - ii) Results and date of diagnostic testing confirming amyloid-β (Aβ) pathology, such as:
 - (1) CSF analysis (t-tau, p-tau, or p-tau/Aβ ratio), OR
 - (2) Amyloid- β PET scan
 - iii) MRI (within one year) prior to initiating treatment to monitor for Amyloid Related Imaging Abnormalities (ARIA)
- c) If referral is incomplete [insert facility protocol, e.g., "notify referring provider to request outstanding clinical documentation"]
- d) Confirm receipt of referral with the referring provider [per facility policy]
- e) Contact patient/care partner to:
 - i) Confirm receipt of referral.
 - ii) Inform the patient/care partner of the next steps and what to expect.
 - iii) Obtain additional information required for referral (e.g., demographic and insurance information).
- f) Begin insurance verification and authorization process.

² The ICD-10 diagnosis codes above may be reasonably related to a diagnosis within the product's approved label. It is not all inclusive, and other codes may be appropriate. NICA does not guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement.

- g) Upon treatment approval, contact the patient/care partner to schedule the lecanemab infusion. When scheduling, discuss the following with the patient: [e.g.:
 - i) Bring a current list of prescriptions and over-the-counter medications (including vitamins and supplements).
 - ii) Make a list of questions for the infusion team.
 - iii) Patient preparation information
 - iv) Facility-specific arrival instructions
 - v) Additional items to bring to appointment, such as a “go bag”]

2) Prior to treatment:

- a) Confirm the patient’s identity using two unique patient identifiers.
- b) Review the medical record to confirm the dose/treatment number.
- c) Provide lecanemab education with the patient/care partner [insert facility patient education policy, e.g., “Provide and review written medication information (e.g., FDA-approved patient medication guide) prior to initial treatment at a minimum, and offer written information prior to each subsequent treatment.”]. Document education in the patient’s medical record.
- d) Verify informed consent is on file. Alternatively, obtain informed consent prior to treatment.
- e) Confirm that the medical record contains complete and current clinical documentation prior to every treatment, including:
 - i) Presence of Aβ pathology prior to initiating treatment (see Section 1.b of this policy).
 - ii) MRI to monitor for ARIA at the following intervals (DO NOT infuse lecanemab if MRI has not been completed):
 - (1) Within one year prior to initiation of treatment
 - (2) Prior to 5th treatment
 - (3) Prior to 7th treatment
 - (4) Prior to 14th treatment
 - iii) Hold the infusion and notify the prescriber if:
 - (1) Document provider notification and orders obtained in the medical record.
- f) Obtain a full set of vital signs [insert facility-specific protocol e.g., “to include blood pressure, pulse, temperature, respiratory rate and oxygen saturation.”]
- g) Hold the infusion and notify the prescriber if:
 - i) Assessment is positive for signs/symptoms of ARIA, such as:
 - (1) Headache
 - (2) Dizziness
 - (3) Nausea
 - (4) Vision changes
 - (5) New or worsening confusion
 - ii) Vital signs are abnormal.
 - iii) MRI has not been completed, or shows radiographic evidence of ARIA.
- h) Measure and record the patient’s weight in kilograms (kg) prior to each treatment³.

³ weight in pounds (lbs) / 2.2 lbs/kg = weight in kg

- i) Calculate the weight-based dose of lecanemab using the patient's actual body weight and recommended lecanemab dose of 10 mg/kg (do not round dose)⁴.
- j) Confirm ordered dose is appropriate based on calculated dose.
- k) Calculate the total volume of lecanemab solution in milliliters (mL) required for ordered dose⁵.
- l) Select lecanemab vials required for the ordered dose, minimizing the amount of wasted drug to the extent possible. Lecanemab is supplied as:
 - i) 500 mg/5 mL solution in a single-dose vial, **AND**
 - ii) 200 mg/2 mL solution in a single-dose vial
- m) Visually inspect vials of lecanemab for particulate matter and discoloration. Lecanemab is clear to opalescent and colorless to pale yellow.
 - i) If particulate matter or discoloration is noted, do not use. Remove from inventory and complete the following:
 - (1) [insert facility protocol e.g., "refer to Adverse Event policy"]
 - (2) Report to [identify responsible party e.g., "nurse manager"].
 - (3) [Responsible party] will notify Eisai medical affairs team of quality concerns at (888) 274-2378 or ESI_MedInfo@eisai.com.
- n) Prior to preparing lecanemab, obtain vascular access [e.g., "per Vascular Access Device Placement policy"].
- o) Gather supplies:
 - i) Gloves
 - ii) Alcohol prep pads
 - iii) Empty syringe (one syringe required for every vial of lecanemab)
 - iv) Blunt fill cannula (one cannula for every new vial of lecanemab)
 - v) Correct number of vial(s) required for lecanemab dose
 - vi) One infusion bag with 250 mL of 0.9% Sodium Chloride Injection, USP
- p) Prepare designated medication preparation area [e.g., "refer to Parenteral Medication Preparation policy," or "disinfect area..." etc.].

3) Medication preparation:

- a) Using aseptic technique:
 - i) Remove the flip-off cap from the vial(s) of lecanemab and disinfect rubber stopper.
 - ii) Insert a sterile blunt fill cannula through the center of the rubber stopper into the lecanemab vial.
 - iii) Withdraw the required volume of lecanemab from the vial(s).
 - iv) Disinfect the injection port of an infusion bag containing 250 mL of 0.9% Sodium Chloride Injection, USP, and slowly inject required volume of lecanemab.
 - v) Discard supplies and any unused portion of lecanemab vial [according to facility policy].
 - vi) Gently invert the infusion bag containing lecanemab to mix completely. Do not shake the bag.
 - vii) Allow the diluted lecanemab to come to room temperature.

⁴ weight in kg x 10 mg/kg = dose (mg)

⁵ total dose (mg)/100 mg/mL = volume required (mL)

viii) Infuse diluted lecanemab immediately. If not able to infuse immediately, may be stored at 2°C to 8°C (36°F to 46°F) for up to 4 hours, after which point it must be discarded.

4) Administration:

- a) Prime the administration set with prepared lecanemab using a terminal low protein binding 0.2 micron in-line filter.
- b) Assess patency of vascular access device (VAD) by [insert facility protocol, e.g., “confirming blood return and flushing with 0.9% Sodium Chloride per Vascular Access policy”].
- c) Disinfect needleless connector and attach the administration set and prepared lecanemab to VAD.
- d) [“Set flow rate” or “program infusion pump”] to infuse the entire volume of diluted lecanemab over at least one hour.
- e) Continually monitor the patient’s treatment tolerance throughout the infusion, assessing for any signs or symptoms of an infusion-related reaction. If an infusion-related reaction is suspected, immediately stop the infusion and [insert facility-specific protocol e.g., “initiate Hypersensitivity Reaction Management Protocol”].
- f) After the infusion is complete, flush the administration set to ensure entire dose including residual volume is administered.
- g) Obtain full set of vital signs.

5) Discharge:

- a) If vital signs are within normal limits and patient is otherwise stable, remove VAD [e.g., “according to facility policy”], document the patient’s treatment tolerance and VAD site assessment.
- b) Review discharge instructions with patient/care partner:
 - i) Expected side effects
 - ii) Symptoms to report and to whom they should be reported.
 - iii) Adverse reactions, whether confirmed or suspected, should be reported to one of the following:
 - (a) Eisai Inc. at (888) 274-2378; or,
 - (b) FDA at (800) FDA-1088 or www.fda.gov/medwatch.
 - iv) Remind the patient/care partner to complete blood work and diagnostic imaging (e.g., MRI), as applicable.
 - v) Encourage patients to participate in the Alzheimer’s Network for Treatment and Diagnostics (ALZ-NET) registry, a voluntary provider-enrolled patient registry that collects information on treatments for Alzheimer’s disease, including lecanemab.

Medication Policy Protocol: This medication policy will be reviewed and updated if necessary [insert facility protocol e.g., “at least annually, or more frequently as necessary.”]

REFERENCES

1. Eisai, Biogen. lecanemab Prescribing Information. 2023.
2. National Infusion Center Association. Standards of Excellence for Ambulatory Infusion Centers (1st ed.). Madison, WI: Omnipress. 2023.