Clinical Policy: Lecanemab-irmb (Leqembi, Leqembi Iqlik)

Reference Number: PA.CP.PHAR.596
Effective Date: 08/2023
Last Review Date: 04/2026

Description
Lecanemab-irmb (Leqembi™, Leqembi Iqlik™) is a monoclonal antibody targeting amyloid beta.

FDA Approved Indication(s)
Leqembi and Leqembi Iqlik are indicated for the treatment of Alzheimer's disease (AD). Treatment with Leqembi and Leqembi Iqlik 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Leqembi and Leqembi Iqlik are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Alzheimer's Disease (must meet all)**:**

1. Diagnosis of MCI due to AD or mild AD dementia (see *Appendix E*);
2. Prescribed by or in consultation with a dementia specialist (e.g., geriatrician, neurologist, or psychiatrist)
3. Documentation of the presence of beta-amyloid plaques as verified by one of the following (a or b):
   a. Positron emission tomography scan;
   b. Cerebrospinal fluid testing;
4. Documentation of one of the following baseline cognitive tests (a, b or c):
   a. Mini-Mental State Examination (MMSE) score of ≥21;
   b. Montreal Cognitive Assessment (MoCA) score of ≥11;
   c. Global Clinical Dementia Rating Scale (CDR) score of 0.5 or 1;
5. Documentation of recent (within the last year) brain magnetic resonance imaging (MRI) demonstrating all of the following (a-d):
   a. 4 or less microhemorrhages (defined as ≤ 10 mm at the greatest diameter);
   b. Absence of any macrohemorrhages > 10 mm at greatest diameter;
   c. Absence of superficial siderosis;
   d. Absence of vasogenic edema, cerebral contusion, encephalomalacia, aneurysms, or vascular malformations;
6. Member has no history of transient ischemic attacks (TIA), stroke, or seizures within the past 12 months;
7. Prescriber attestation that the prescriber has discussed with the member the potentially increased risk of amyloid-related imaging abnormalities (ARIA) in those

who are ApoE4 genetic homozygotes and in those who are currently taking, or who may eventually need, concomitant anticoagulant or antiplatelet therapy;
8. Leqembi or Leqembi Iqlik is not prescribed concurrently with Kisunla™;
9. Dose does not exceed 10 mg/kg every 2 weeks.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Alzheimer's Disease (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by improvement or slowed decline in cognition OR the member continues to experience medical benefit based on the prescriber's assessment;
3. Documentation of recent (within the last month) results of one of the following cognitive/functional tests within the last month (a, b, c, d or e):
   a. Mini-Mental State Examination (MMSE) score of ≥21;
   b. Montreal Cognitive Assessment (MoCA) score of ≥11;
   c. Global Clinical Dementia Rating Scale (CDR) score of 0.5 or 1;
   d. Functional Assessment Staging Test (FAST) score of ≤4;
   e. Clinical Dementia Rating-Sum of Boxes (CDR-SB) score of ≤9;
4. Leqembi or Leqembi Iqlik is not prescribed concurrently with Kisunla;
5. If request is for a dose increase, new dose does not exceed any of the following (a or b:)
   a. IV infusions: 10 mg/kg once every 2 weeks;
   b. SC injections: 360 mg once weekly.

   Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AD: Alzheimer's disease
ARIA: amyloid-related imaging abnormalities
CDR-SB: Clinical Dementia Rating-Sum of Boxes
FAQ: Functional Assessment Questionnaire
FAST: Functional Assessment Staging Test
FDA: Food and Drug Administration
IADL: instrumental activity of daily living
MCI: mild cognitive impairment
MMSE: Mini-Mental State Examination
MoCA: Montreal Cognitive Assessment
MRI: magnetic resonance imaging
TIA: transient ischemic attack

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): serious hypersensitivity to lecanemab-irmb or to any of the excipients of Leqembi or Leqembi Iqlik
- Boxed Warning(s): increased risk of ARIA

Appendix D: Dementia Rating Scales

- MoCA is a highly sensitive tool for early detection of MCI and has been widely adopted in clinical settings. The maximum score is 30 points. The average MoCA score for MCI is 22 (range 19-25) and the average MoCA score for Mild AD is 16 (range 11-21).
- MMSE is a series of questions asked by a health professional designed to test a range of everyday mental skills. The maximum score is 30 points where the following levels of dementia are indicated with a score of:
  - 25 to 30 suggests normal cognition,
  - 21 to 24 suggests mild dementia,
  - 13 to 20 suggests moderate dementia, and
  - less than 12 indicates severe dementia.
  - On average, the MMSE score of a person with Alzheimer's declines about two to four points each year.
- The FAQ measures instrumental activities of daily living (IADLs), such as preparing balanced meals and managing personal finances. Since functional changes are noted earlier in the dementia process with IADLs that require a higher cognitive ability compared to basic activities of daily living, this tool is useful to monitor these functional changes over time. The score range is 0-30. A cut-point of 9 (dependent in 3 or more activities) is recommended to indicate impaired function and possible cognitive impairment.
- FAST is a measure commonly used to assess functional status in patients with dementia. It provides a comprehensive evaluation of functional ability and the potential for a functional decline over time, including physical functional abilities (dressing and grooming), functional language abilities (memory and recognition), and functional activities such as mobility or self-feeding. The FAST score ranges from 1 to 7, categorizing the stages of AD into one of the below:

  - 1: normal aging
  - 2: possible mild cognitive impairment
  - 3: mild cognitive impairment
  - 4: mild dementia
  - 5: moderate dementia
  - 6: moderately severe dementia
  - 7: severe dementia
- CDR-SB assessment is a 5-point scale used to characterize six domains of cognitive and functional performance applicable to Alzheimer's disease and related dementias: memory, orientation, judgment and problem solving, community affairs, home and hobbies, and personal care. The information is obtained through an interview of the patient and a reliable informant (e.g., family member). This score is useful for characterizing and tracking a patient's level of impairment/dementia.
  - 0 suggests normal
  - 0.5 to 4 suggests questionable cognitive impairment
  - 0.5 to 2.5 suggests questionable impairment
  - 3.0 to 4.0 suggests very mild dementia
  - 4.5 to 9.0 suggests mild dementia
  - 9.5 to 15.5 suggests moderate dementia
  - 16.0 to 18.0 suggests severe dementia

Appendix E: Diagnosis of Alzheimer's Disease

- AD
  - Interference with ability to function at work or at usual activities
  - A decline from a previous level of functioning and performing
  - Not explained by delirium or major psychiatric disorder
  - Cognitive impairment established by history-taking from the patient and a knowledgeable informant; and objective bedside mental status examination or neuropsychological testing
  - Cognitive impairment involves a minimum of two of the following domains:
    - Impaired ability to acquire and remember new information
    - Impaired reasoning and handling of complex tasks, poor judgment
    - Impaired visuospatial abilities
    - Impaired language functions (speaking, reading, writing)
    - Changes in personality, behavior, or comportment
  - Insidious onset (gradual onset over months to years, not over hours to days)
  - Clear-cut history of worsening
  - Initial and most prominent cognitive deficits are one of the following:
    - Amnestic presentation (impairment in learning and recall of recently learned information)
    - Nonamnestic presentation in either a language presentation (prominently word-finding deficits), a visuospatial presentation with visual deficits, or executive dysfunction (prominently impaired reasoning, judgment and/or problem solving)
  - No evidence of substantial concomitant cerebrovascular disease, core features of dementia with Lewy bodies (DLB), prominent features of behavioral variant frontotemporal dementia (FTD) or prominent features of semantic or

nonfluent/agrammatic variants of primary progressive aphasia (PPA), or evidence of another concurrent, active neurologic or non-neurologic disease or use of medication that could have a substantial effect on cognition

- MCI due to AD – core clinical criteria
  - Concern regarding change in cognition obtained from the patient, from an informant who knows the patient well, or from a skilled clinician observing the patient
  - Objective evidence of impairment in one or more cognitive domains that is not explained by age or education
  - Preservation of independence in functional abilities
  - Not demented
- Although tests for blood-based biomarkers are now available to aid in diagnosing Alzheimer's disease, their proper use in clinical practice is unestablished. They are not currently able to fully replace the need for confirmatory testing with positron emission tomography scan or cerebrospinal fluid testing, and as such, their ability to determine eligibility for treatment with Leqembi is unconfirmed.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AD	**IV infusions:** 10 mg/kg IV every 2 weeks After 18 months, the regimen of 10 mg/kg IV every 2 weeks may be continued, or a transition to the maintenance dosing regimen of 10 mg/kg IV every 4 weeks may be considered. **SC injections:** 360 mg SC every week	IV: 10 mg/kg every 2 weeks SC: 360 mg/week

VI. Product Availability

Drug Name	Availability
Lecanemab-irmb (Leqembi, Leqembi Iqlik)	Vials for injection (single-dose): 200 mg/2 mL, 500 mg/5 mL Single-dose prefilled autoinjector: 360 mg/1.8 mL (200 mg/mL)

VII. References

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6. Trzepacz PT, Hochstetler H, Wang S, et al. Relationship between the Montreal Cognitive Assessment and Mini-Mental State Examination for assessment of mild cognitive impairment in older adults. BMC Geriatrics 2015;15:107. https://doi.org/10.1186/s12877-015-0103-3.
7. O'Bryant SE, Waring SC, Cullum CM, et al. Staging dementia using Clinical Dementia Rating Scale Sum of Boxes Scores: a Texas Alzheimer's Research Consortium study. Arch Neurol 2008 August;65(8):1091–1095. doi:10.1001/archneur.65.8.1091.
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11. Jack CR, Andrews JS, Beach TG, et al. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. Alzheimer's Dement. 2024;20:5143-69. doi: 10.1002/alz.13859.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0174	Lecanemab-irmb, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	07/2023
4Q 2024 annual review: no significant changes; clarified the covered indication as "MCI *due to AD*" to align with the Kisunla criteria; added exclusion against concomitant use with Kisunla; clarified for the reauth duration that infusions up to the 13th total infusion will be authorized for members with < 14 total infusions but ≥ 7 total infusions (instead of > 7 total infusions) to encompass those who have had a total of exactly 7 infusions by that point in time; references reviewed and updated.	10/2024
Removed the age limit of 50-90 years of age. Updated the maintenance dosing regimen to include the option for every 4 week dosing after the initial 18 months of therapy, per the Prescribing Information.	04/2025
4Q 2025 annual review: for Continued Therapy criteria, clarified that the neurocognitive testing results used for coverage redetermination should be	10/2025

Reviews, Revisions, and Approvals	Date
"recent (within the last month)" to ensure that Leqembi continues to be used only for those who remain in the mild stage of disease; updated the requirement for follow-up pre-infusion MRIs to be done within the prior week instead of within the prior month per the updated Leqembi Prescribing Information; added dosing and auth limits for newly FDA-approved SC Leqembi Iqlik to the criteria; references reviewed and updated.	
Removed the requirement for follow-up MRIs in the Continued Therapy section; added Leqembi Iqlik as a recently FDA-approved alternative formulation of Leqembi that should not be used concomitantly with Kisunla; extended initial and continued approval durations to 6 and 12 months, respectively.	04/2026