Clinical Policy: Lecanemab-irmb (Leqembi)

Reference Number: CP.PHAR.596
Effective Date: 01.06.23
Last Review Date: 11.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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 geriatrician or neurologist;
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 or b; *see Appendix D*):
   a. Mini-Mental State Examination (MMSE) score ≥ 22;
   b. Montreal Cognitive Assessment (MoCA) score ≥ 16;
5. Documentation of one of the following baseline functional tests and the resulting score (a, b, or c):
   a. Functional Assessment Questionnaire (FAQ) score ≤ 9;
   b. Functional Assessment Staging Test (FAST) score of 3-4;
   c. Clinical Dementia Rating-Sum of Boxes (CDR-SB) of 0.5-9;
6. Documentation of recent (within the last year) brain magnetic resonance imaging (MRI) demonstrating all of the following (a-d):
   a. Fewer than 4 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;

7. Member has no history of transient ischemic attacks (TIA), stroke, or seizures within the past 12 months;
8. Member is not currently taking concomitant anticoagulant or antiplatelet therapy;
9. 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;
10. Leqembi is not prescribed concurrently with Kisunla™;
11. Dose does not exceed 10 mg/kg every 2 weeks.

Approval duration: 3 months (6 doses of IV infusion only)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*;
2. Member is responding positively to therapy as evidenced by slowed decline in cognition;
3. Documentation of recent (within the last month) results of one of the following cognitive tests (a or b; *see Appendix D*):
   a. MMSE score ≥ 22;
   b. MoCA score ≥ 16;

4. Documentation of recent (within the last month) results of one of the following functional tests and the resulting score (a, b, or c):
   a. FAQ score ≤ 9;
   b. FAST score of 3-4;
   c. CDR-SB of 0.5-9;
5. Prior to the 7th and 14th infusions, documentation of a recent (within the last week) brain MRI showing all of the following (a, b, and c):
   a. Absence of any macrohemorrhage (> 10 mm at greatest diameter; symptomatic or not);
   b. Fewer than 10 cerebral microhemorrhages cumulatively (symptomatic or not);
   c. Absence of symptomatic cerebral microhemorrhages or symptomatic superficial siderosis;
6. Member is not currently taking concomitant anticoagulant or antiplatelet therapy;
7. Leqembi or Leqembi Iqlik are not prescribed concurrently with Kisunla;
8. 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:

- **Members with < 7 total IV infusions: up to the 6th total IV infusion**
- **Members with < 14 total IV infusions but ≥ 7 total IV infusions: up to the 13th total infusion**
- **Members with ≥ 14 total IV infusions: 12 IV infusions per PA approval through the first 18 months of Leqembi therapy**
- **After 18 total months of Leqembi IV therapy: 12 months**

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

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 following ranges may be used to grade severity: 18-25 = mild cognitive impairment, 10-17 = moderate cognitive impairment and < 10 = severe cognitive impairment. However, research for these severity ranges has not been established yet. 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.
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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, for intravenous injection, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	10.04.22	11.22
Drug is now FDA approved - criteria updated per FDA labeling: added specialist requirement, added attestation that the prescriber has discussed the potentially increased risk of ARIA in ApoE4 homozygotes and with concomitant anticoagulants/antithrombotics, separated Commercial LOB into a separate policy (see CP.CPA.358); references reviewed and updated.	01.10.23	02.23
Previously granted accelerated approval is now converted to full (traditional) FDA approval – criteria updated per FDA labeling and CMS patient registry requirements: for Initial Approval Criteria, removed the requirement for enrollment in an NIH-sponsored trial; added requirements around cognitive testing (MoCA or MMSE) and functional testing (FAQ, FAST, or CDR-SB) to align with required elements of the CMS-sponsored patient registry; added a requirement for baseline MRI and history of stroke, TIA, and seizures to identify patients at increased risk for ARIA; added an exclusion for use with concomitant anticoagulant or antiplatelet therapy; for Continued Therapy, removed the requirement for enrollment in an NIH-sponsored trial; added a requirement for follow-up MRI results to identify new-onset ARIA; added requirement for cognitive and functional testing results to confirm that the member has not progressed beyond the mild stage of AD; added an exclusion for use with concomitant anticoagulant or antiplatelet therapy; added max dosing limits and Approval Durations; updated Boxed Warnings to include the new warning re: ARIA; combined Commercial policy (CP.CPA.358) with this policy since the coverage criteria across all LOBs is now the same, Commercial policy will be retired; new Jcode added; references reviewed and updated.	07.12.23	08.23
4Q 2023 annual review: no significant changes; recent full review completed at 3Q 2023 P&T after conversion of Leqembi's accelerated approval to full approval.	08.08.23	11.23
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.	08.07.24	11.24
Removed the age limit of 50-90 years of age.	10.25.24	12.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.	03.11.25	05.25
In the Continued Therapy section, removed the word "baseline" in reference to the required cognitive and functional tests to ensure that Leqembi therapy is not continued in those who have progressed to the moderate stage of disease severity.	05.01.25	06.25
4Q 2025 annual review: for Continued Therapy criteria, clarified that the neurocognitive testing results used for coverage redetermination should be "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.	09.02.25	11.25
HCPCS code description revised [J0174].	02.18.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.