Leqembi (lecanemab-irmb) Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Leqembi (lecanemab-irmb)		
Classification: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)		
MNG #:	☒ **SCO** ☒ **One Care** ☒ **MA Medicare Preferred** ☒ **MA Medicare Value** ☒ **RI Medicare Preferred** ☒ **RI Medicare Value** ☒ **RI Medicare Maximum**	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Benefit Type: ☒ **Medicare** ☐ **Medicaid**	**Approval Date:** 9/14/23	**Effective Date:** 9/14/23; 11/14/24
Last Revised Date: 10/10/24; 11/14/24	**Next Annual Review Date:** 9/14/24; 10/10/25	**Retire Date:**

OVERVIEW:

Alzheimer disease (AD) is a neurodegenerative disorder of uncertain cause and pathogenesis that primarily affects older adults and is the most common cause of dementia. The most essential and often earliest clinical manifestation of AD is selective memory impairment, although there are exceptions. While treatments are available that can improve some symptoms of the illness, there is no cure, and the disease inevitably progresses in all individuals.

The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. Amyloid-targeted therapy refers to recombinant monoclonal antibodies directed against amyloid beta. These agents are highly effective at reducing amyloid plaque burden on positron emission tomography (PET) imaging and are therefore believed to be disease modifying. However, the efficacy in regard to clinical outcomes is modest.

Lecanemab-irmb is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. Individuals with AD who have mild AD dementia or mild cognitive impairment due to AD may be offered Lequembi if selection criteria are met, and the individual has no contraindications to treatment. Monoclonal antibodies directed against aggregated forms of amyloid beta are associated with risk for significant adverse effects, including amyloid related imaging abnormalities (ARIA). Individuals who are apolipoprotein E ε4 (ApoE ε4) homozygotes treated with this class of medications, including Lequembia, have a higher incidence of ARIA.

DECISION GUIDELINES:

Medical records documenting confirmed evidence of clinically significant AD neuropathology should include one of the following:

- Cerebral spinal fluid (CSF) biomarkers; or
- Amyloid positron emission tomography (PET); and

Leqembi (lecanemab-irmb) Medical Necessity Guideline

Medical records documenting baseline (within the last three months) cognitive function should be based on one of the following objective assessments;

- Mini Mental State Exam (MMSE) score ≥ 22; or
- Montreal Cognitive Assessment (MoCA) score ≥ 15; or
- St. Louis University Mental Status Examination (SLUMS) score ≥ 16.1.

Clinical Coverage Criteria:

Commonwealth Care Alliance (CCA) may authorize coverage of Leqembi (Lecanemab-irmb) when all the following criteria are met**:**

NOTE: Initial authorization of Leqembi is limited to a total of 6 months if initial authorization criteria are met.

1. **INITIAL AUTHORIZATION CRITERIA:**

Initial 6 months of treatment

a. Documentation submitted confirms the diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) or mild AD dementia; and
b. Confirmation that the member has presence of amyloid beta pathology consistent with AD prior to initiating treatment; and
c. Prescribing physician participates in a qualifying registry with an appropriate clinical team and follow-up care.

2. **REAUTHORIZATION CRITERIA:** CCA may re-authorize coverage of Leqembi when all the following criteria are met:

Re-authorized for an additional 12 months beyond the initial 6-month authorization

a. Member has met all initial authorization criteria at the time of initial approval; and
b. Member is monitored for ARIA (amyloid-related imaging abnormalities):
   i. Member has been evaluated for evidence of ARIA on MRI prior to the 5th dose, 7th dose, and 14th dose; and
   ii. If member experiences symptoms suggestive of ARIA, clinical evaluation, including an MRI if indicated, has been performed; and
   iii. Recommendations for Dosing Interruptions in Patients with ARIA per FDA prescribing information are followed as applicable

LIMITATIONS/EXCLUSIONS: CCA will not cover

Leqembi (lecanemab-irmb) Medical Necessity Guideline

1. Leqembi for an earlier or later stages of Alzheimer's Disease
2. Monoclonal antibodies directed against amyloid for the treatment of AD provided outside of an FDA approved randomized controlled trial, CMS-approved studies, or studies supported by the NIH, are nationally non-covered.
3. Leqembi for suspected or confirmed neurodegenerative diseases of cognitive impairment other than Alzheimer's disease (AD), including but not limited to frontotemporal lobar degeneration (FTLD) or Lewy body disease (i.e., meeting consensus criteria for possible or probable dementia with Lewy bodies).
4. Leqembi will not be used in combination with any other amyloid beta-directed antibodies

CODING:

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

CPT/HCPCS CODE	CODE DESCRIPTION
J0174	Injection, lecanemab-irmb, 1mg

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists. Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity [supporting literature (full text preferred) should be attached to the request], or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

1. Centers for Medicare & Medicaid Services. Press Release: Statement: Broader Medicare Coverage of Leqembi Available Following FDA Traditional Approval. July 6, 2023.
2. Accessed September 30, 2024. NCD - Monoclonal Antibodies Directed Against Amyloid for the Treatment of

Alzheimer's Disease (AD) (200.3) (cms.gov)

3. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 200.3. Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD). Accessed September 30, 2024. (cms.gov)
4. Centers for Medicare & Medicaid Services. Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD). Accessed September 30, 2024. https://www.cms.gov/medicare/coverage-evidence- development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad
5. Prospective Study on Anti-Amyloid-β Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Coverage of Evidence Development (The Anti-Aβ mAb CED Study), Clinicaltrials.gov number: NCT05925621, CMS Approval Date 07/11/23: https://www.cms.gov/files/document/ced-study-description.pdf
6. Wolk DA, MD, Dickerson BC, MD. Clinical features and diagnosis of Alzheimer disease. Accessed by subscription UpToDate September 30, 2024. https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-alzheimer-disease?search=alzheimer%20treatment&source=search_result&selectedTitle=2%7E150&usage_type=default&display_rank=2
7. Mendez MF, MD, PhD. Mental status scales to evaluate cognition. Accessed September 30, 2024 by subscription UpToDate. https://www.uptodate.com/contents/mental-status-scales-to-evaluate-cognition?search=Mental%20status%20scales%20to%20evaluate%20cognition&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
8. Larson EB, MD, MPH. Evaluation of cognitive impairment and dementia. Accessed by subscription UpToDate September 30, 2024. https://www.uptodate.com/contents/evaluation-of-cognitive-impairment-and-dementia?search=alzheimer%20treatment&topicRef=14067&source=see_link
9. Cohen S, van Dyck CH, Gee M, et al. Lecanemab Clarity AD: Quality-of-Life Results from a Randomized, Double-Blind Phase 3 Trial in Early Alzheimer's Disease. *J Prev Alzheimers Dis*. 2023;10(4):771-777. doi:10.14283/jpad.2023.123
10. Alzheimer's Association. Mild Cognitive Impairment (MCI). Accessed September 30, 2024.https://www.alz.org/alzheimers-dementia/what- is-dementia/related_conditions/mild-cognitive-impairment#:~:text=Mild%20cognitive%20impairment%20(MCI)%20is,most%20activities%20of%20daily%20living.
11. AA 2021, NIA 2021, CDC 2021, Rajan 2021, Brookmeyer 2018, 2019.
12. Mass Health Alzheimer's Agents – Anti-Amyloid Monoclonal Antibodies; Evaluation Criteria for Approval Lequembi. Accessed September 30, 2024. https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=2177&drugId=8605
13. Gallegos M, Morgan ML, Cervigni M, et al. 45 Years of the mini-mental state examination (MMSE): A perspective from ibero-america. *Dement Neuropsychol*. 2022;16(4):384-387. Published 2022 Jul 29. doi:10.1590/1980-5764-DN-2021-0097
14. Albert MS, DeKosky ST, Dickson D, et al. The diagnosis of mild cognitive impairment due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. *Alzheimers Dement*. 2011;7(3):270-279. doi:10.1016/j.jalz.2011.03.008
15. Arevalo-Rodriguez I, Smailagic N, Roqué-Figuls M, et al. Mini-Mental State Examination (MMSE) for the early detection of dementia in people with mild cognitive impairment (MCI). *Cochrane Database Syst Rev*. 2021;7(7):CD010783. Published 2021 Jul 27. doi:10.1002/14651858.CD010783.pub3
16. APA GUIDELINES for the Evaluation of Dementia and Age-Related Cognitive Change APA TASK FORCE ON THE

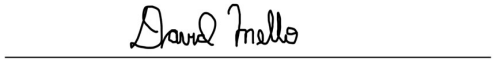
Leqembi (lecanemab-irmb) Medical Necessity Guideline

EVALUATION OF DEMENTIA AND AGE-RELATED COGNITIVE CHANGE APPROVED BY APA. Accessed September 30, 2024. https://www.apa.org/practice/guidelines/guidelines-dementia-age-related-cognitive-change.pdf

REVISION LOG:

REVISION DATE	DESCRIPTION
11/14/24	Added documentation requirements for AD neuropathology and cognitive status
10/10/24	Update to overview section, updated criteria to align with NCD/FDA indications, added additional criteria re: ARIA monitoring for re-authorization

APPROVALS:

David Mello	Senior Medical Director Utilization Review and Medical Policy
CCA Clinical Lead	**Title**
	11/14/24
Signature	**Date**
CCA Senior Operational Lead	**Title**
Signature	**Date**
Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee	**Title**
	11/14/24
Signature	**Date**

Leqembi (lecanemab-irmb) Medical Necessity Guideline

2024