POLICY: Neurology – Leqembi Utilization Management Medical Policy

- Leqembi™ (lecanemab-irmb intravenous infusion – Eisai/Biogen)

EFFECTIVE DATE: 05/15/2023
LAST REVISION DATE: 03/11/2025

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

SUMMARY OF EVIDENCE

Leqembi, an amyloid beta-directed antibody, is indicated for the **treatment of Alzheimer's disease** in patients with mild cognitive impairment or mild dementia stage of disease.[1]

Disease Overview

An estimated 6.9 million Americans ≥ 65 years of age are living with Alzheimer's dementia in 2024, with 73% of these people ≥ 75 years of age.[2] The number and proportion of older adults who have mild cognitive impairment due to Alzheimer's disease is difficult to estimate; however, a rough approximation suggests that 5 to 7 million older Americans may have mild cognitive impairment due to Alzheimer's disease. People with mild cognitive impairment due to Alzheimer's disease have biomarker evidence of brain changes due to the disease in addition to subtle problems with memory and thinking. Biomarker evidence includes abnormal levels of amyloid beta as evidenced on positron emission tomography (PET) scans and in analysis of cerebrospinal fluid, and decreased metabolism of glucose as shown on PET scans. These cognitive problems may be noticeable to the individual family members and friends, but not to others, and they do not interfere with the person's ability to carry out everyday activities. The mild changes in cognitive abilities occur when the brain can no longer compensate for the damage and death of nerve cells due to Alzheimer's disease. Among those with mild cognitive impairment, about 15% develop dementia after 2 years. Approximately one-third of people with mild cognitive impairment develop Alzheimer's dementia within 5 years.

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Leqembi. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or

LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Leqembi is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Alzheimer's Disease. #**

Criteria. Approve for 1 year if the patient meets the following (A, B and C):

A) The patient has a clinical diagnosis of mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease **[documentation required]**; AND

B) The presence of amyloid beta pathology consistent with Alzheimer's disease has been confirmed **[documentation required]**; AND

C) The patient meets one of the following (i or ii):

i. The patient is receiving the requested medication as part of a prospective comparative study **[documentation required]** AND the study is CMS-approved **[documentation required]**; OR

ii. The patient is receiving the requested medication as part of a clinical trial **[documentation required]** AND the trial is supported by the National Institutes of Health (NIH) **[documentation required]**.

Dosing. Approve the following dosing: 10 mg/kg administered as an intravenous (IV) infusion once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Leqembi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SOURCES OF INFORMATION

1. Leqembi® intravenous infusion [prescribing information]. Nutley, NJ: Eisai; January 2025.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2024. Available at: https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf. Accessed on January 27, 2025.
3. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody. *Alzheimers Res Ther*. 2021;13(1):80.
4. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388(1):9-21.
5. Andrews JS, Desai U, Kirson NY, et al. Disease severity and minimal clinically important differences in clinical outcome assessments for Alzheimer's disease clinical trials. *Alzheimers Dement*. 2019;5:354-363.
6. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) 200.3. [Version Number 1, Effective date: 04/07/2022. Revision date: 10/2024. Accessed March 11, 2025.
7. Centers for Medicare and Medicaid Services. Fact Sheet: CMS announces new details of plan to cover new Alzheimer's drugs. https://www.cms.gov/newsroom/fact-sheets/cms-announces-new-details-plan-cover-new-alzheimers-drugs - Issued 06/22/2023. Accessed February 22, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/05/2023
Policy revision	Removed the following criteria, secondary to Leqembi receiving traditional FDA approval: The patient is receiving the requested medication as part of a randomized controlled trial **[documentation required]** AND the trial is conducted under an investigational new drug (IND) application **[documentation required]**	08/02/2023
Policy review	No criteria changes (based on review of commercial policy review)	02/22/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Policy review	No criteria changes. Review based on NCD surveillance review.	01/07/2025
Policy review	No criteria changes. Review based on commercial policy annual review	02/18/2025
Policy revision	No criteria changes. Formatting and notation updates.	03/11/2025