



PHARMACY POLICY STATEMENT

HAP CareSource™ Marketplace

DRUG NAME	Leqembi (lecanemab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Leqembi is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment should be initiated in patients with mild cognitive impairment or mild dementia stage of disease (stage 3 or 4), the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages.

Leqembi was granted accelerated approval by the FDA in January 2023 based on reduction in amyloid beta plaques observed in patients treated with Leqembi in a phase 2 clinical trial. Upon reviewing data from the phase 3 CLARITY AD trial that confirmed a clinical benefit, the FDA converted the accelerated approval to a traditional approval in July 2023.

Leqembi is a monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. Leqembi reduces amyloid beta plaques, with high selectivity for the soluble aggregated species. Alzheimer's disease, the most common cause of dementia, is a progressive, irreversible neurodegenerative disease associated with cognitive, functional, and behavioral impairments.

Leqembi has a black box warning for amyloid related imaging abnormalities (ARIA). ApoE ε4 homozygotes have a higher incidence of ARIA.

Leqembi (lecanemab) will be considered for coverage when the following criteria are met:

Alzheimer's Disease

For **initial** authorization:

1. Member is at least 50 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or geriatrician; AND
3. Member has a diagnosis of early Alzheimer's disease with mild cognitive impairment due to Alzheimer's disease OR mild Alzheimer's disease-related dementia (on the basis of National Institute on Aging-Alzheimer's Association criteria (NIA-AA)^{2,3}); AND
4. Presence of amyloid beta pathology has been confirmed by one of the following:
 - a) Positron-emission tomography (PET) scan imaging
 - b) Cerebrospinal fluid (CSF) lumbar puncture; AND
5. Documentation of Mini mental state examination (MMSE) score of 22 to 30; AND
6. Documentation of global Clinical Dementia Rating (CDR) global score of 0.5 or 1.0 and CDR Memory Box score of 0.5 or greater; AND
7. Member has had a brain MRI in the past 12 months to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA); AND
8. Member's ApoE ε4 status has been or will be determined before starting treatment (must provide documentation of results or pending order for testing); AND
9. Member does NOT have any of the following:



- a) Transient ischemic attacks (TIA), stroke, or seizures within the last 12 months
- b) Contraindication to MRI
- c) Inadequately controlled bleeding disorder
- d) Taking an anticoagulant.

10. **Dosage allowed/Quantity limit:** 10 mg/kg IV infusion every 2 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

- 1. Member has had a follow up assessment including cognitive test(s) to determine that they have not progressed to moderate/severe dementia; AND
- 2. Documentation of continued MRI monitoring for amyloid related imaging abnormalities -edema (ARIA-E) and -hemosiderin deposition (ARIA-H), as per prescribing information.

If all the above requirements are met, the medication will be approved for an additional 6 months.

HAP CareSource considers Leqembi (lecanemab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
02/22/2023	New policy for Leqembi created.
07/17/2023	Added reference (Cummings 2023). Added requirement for ApoE ε4 testing per updated prescribing information following conversion of accelerated approval to traditional approval status. Removed Wechsler memory score.

References:

- 1. Leqembi. [prescribing information]. Eisai Inc.; July 2023.
- 2. 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
- 3. McKhann GM, Knopman DS, Chertkow H, et al. The diagnosis of dementia 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):263-269. doi:10.1016/j.jalz.2011.03.005
- 4. Porsteinsson AP, Isaacson RS, Knox S, Sabbagh MN, Rubino I. Diagnosis of Early Alzheimer's Disease: Clinical Practice in 2021. *J Prev Alzheimers Dis*. 2021;8(3):371-386. doi:10.14283/jpad.2021.23
- 5. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in Early Alzheimer's Disease. *N Engl J Med*. 2023;388(1):9-21. doi:10.1056/NEJMoa2212948
- 6. 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 [published correction appears in *Alzheimers Res Ther*. 2022 May 21;14(1):70]. *Alzheimers Res Ther*. 2021;13(1):80. Published 2021 Apr 17. doi:10.1186/s13195-021-00813-8
- 7. McDade E, Cummings JL, Dhadda S, et al. Lecanemab in patients with early Alzheimer's disease: detailed results on biomarker, cognitive, and clinical effects from the randomized and open-label extension of the phase 2 proof-of-concept study. *Alzheimers Res Ther*. 2022;14(1):191. Published 2022 Dec 21. doi:10.1186/s13195-022-01124-2
- 8. Reardon S. FDA approves Alzheimer's drug lecanemab amid safety concerns. *Nature*. 2023;613(7943):227-228. doi:10.1038/d41586-023-00030-3
- 9. ALZFORUM. Dare We Say Consensus Achieved: Lecanemab Slows the Disease. 09 Dec 2022. <https://www.alzforum.org/news/conference-coverage/dare-we-say-consensus-achieved-lecanemab-slows-disease>



10. Centers for Medicare & Medicaid Services (CMS): Medicare Coverage Database. Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD). National Coverage Determination (NCD). 04/07/2022. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1>
11. Cummings J, Apostolova L, Rabinovici GD, et al. Lecanemab: Appropriate Use Recommendations. *J Prev Alzheimers Dis*. 2023;10(3):362-377. doi:10.14283/jpad.2023.30

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Revised date: 07/17/2023