

Policy Name:	Leqembi (lecanemab)	Policy#:	3214P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Leqembi (lecanemab).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Leqembi (lecanemab) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of mild cognitive impairment related to Alzheimer disease or mild Alzheimer disease dementia
 - Functional Assessment Staging Test (FAST) Stage score of 2-4, meeting criteria for mild cognitive impairment or mild Alzheimer disease dementia
- 1.2 Documented evidence of beta-amyloid plaques on the brain through PET imaging and/or cerebrospinal fluid (CSF) analysis
- 1.3 Prescribed by a neurologist (nervous system doctor), geriatric psychiatrist (mental health physician specializing in treating elderly patients), or geriatrician (elder patient doctor) who specializes in treating dementia
- 1.4 Physician participates in a qualifying registry with appropriate clinical team/follow-up care plan
- 1.5 Documentation to support mild cognitive decline such as Mini-Mental State Examination (MMSE) ≥ 19 , Montreal Cognitive Assessment (MoCA) ≥ 17 , or clinical dementia rating (CDR) 0.5 to 1

2. Exclusion Criteria

- 2.1 Documentation of any amyloid-related imaging abnormalities (ARIA), such as brain swelling or brain bleeds
- 2.2 Coverage of Aduhelm is considered experimental at this time and excluded from coverage
- 2.3 Administration outside of a qualifying registry are excluded from coverage

3. Approval Period

- 3.1 Initial approval: 12 months
- 3.2 Subsequent approvals: 12 months with clinical documentation to support slowed decline of cognition and function

CPT Codes

HCPCS Codes

J0174	Injection, lecanemab-irmb, 1 mg
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References

1. Leqembi (lecanemab) [prescribing information]. Nutley, NJ: Eisai Inc; July 2023.
2. 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 Dec 21;14(1):191.
3. Cohen S, van Dyck CH, Gee M, Doherty T, Kanekiyo M, Dhadda S, Li D, Hersch S, Irizarry M, Kramer LD. 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.
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. American Psychiatric Association Practice Guideline for the Treatment of Patients with Alzheimer's disease and Other Dementias. American Psychiatric Association Practice Guideline for the Treatment of Patients with Alzheimer's disease and Other Dementias.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1- 800-851-3379 for verification of coverage.