Mass General Brigham
Health Plan

Leqembi IQLIK (lecanemab-irmb)
Effective 03/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Leqembi (lecanemab-irmb) is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease.

Leqembi is available as an intravenous formulation as well as a subcutaneous injection (IQLIK). After 18 months of treatment of the IV, patients can continue on the IV formulation or transition to the subcutaneous formulation.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

1. Documentation of one of the following diagnoses:
    a. Mild cognitive impairment due to Alzheimer's disease
    b. Mild dementia due to Alzheimer's disease
2. Member is 18 years of age or older
3. Requested medication is prescribed by, or in consultation with, a specialist in neurology or gerontology
4. Documentation member has received Leqembi IV for at least 18 months and the SC injection will be used as maintenance therapy moving forward
5. The SC formulation will not be used in combination with the IV
6. Documentation the member has responded to IV therapy compared to pretreatment baseline, as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in at least one assessment tool (e.g., ADAS-Cog 13/14, ADCS-ADL-MCI, MMSE, CDR-SB, MoCA)
7. Documentation the member has not progressed to moderate to severe Alzheimer's disease
8. Documentation the requested medication will not be used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Kisunla)

Continuation of Therapy
Requests for reauthorization will be approved when all of the following criteria are met:

1. Documentation the member has not progressed to moderate to severe Alzheimer's disease

2. Documentation the member has responded to therapy compared to pretreatment baseline, as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in at least one assessment tool (e.g., ADAS-Cog 13/14, ADCS-ADL-MCI, MMSE, CDR-SB, MoCA)
3. Documentation the requested medication will not be used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Kisunla)
4. SC formulation will not be used in combination with the IV formulation
5. Requested medication is prescribed by, or in consultation with, a specialist in neurology or gerontology

Limitations

1. Initial and reauthorization approvals will be granted for 6 months

References

1. Alawode DOT, Fox NC, Zetterberg H, Heslegrave HJ. Alzheimer's disease biomarkers revisited from amyloid cascade hypothesis standpoint. *Front Neurosci*. 2022;16(837390):1-14.
2. 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.
3. Arvanitakis Z, Shah RC, Bennett DA. Diagnosis and management of dementia: a review. *JAMA*. 2019;322(16):1589-1599.
4. Atri A. The Alzheimer's disease clinical spectrum diagnosis and management. *Med Clin N Am*.
5. CMS announces plan to ensure availability of new Alzheimer's drugs [press release on the internet]. Baltimore (MD): Centers for Medicare and Medicaid Services; 2023 Jun 1 [cited 2023 Jun 16]. Available from: https://www.cms.gov/newsroom/press-releases/cms-announces-plan-ensure-availability-new-alzheimers-drugs.
6. Cummings J, Lee G, Nahed P, et al. Alzheimer's disease drug development pipeline: 2022. *Alzheimer's Dement.* 2022;8:e12295.
7. Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388:9-21.
8. Hyman BT, Phelps CH, Beach TG, et al. National Institute on Aging-Alzheimer's Association guidelines for the neuropathic assessment of Alzheimer's disease. *Alzheimers Dement*. 2012;8(1):1-13.
9. Iqbal K, Liu F, Gong CX, et al. Tau in Alzheimer's Disease and related tauopathies. *Curr Alzheimer Res*. 2010;7(8): 656-664.
11. Lansdall CJ, McDougall F, Butler LM, et al. Establishing clinically meaningful change on outcome assessments frequently used in trials with mild cognitive impairment due to Alzheimer's disease. *J Prev Alz Dis*; 2023;1(10):9-18.
12. Leqembi (lecanemab-irmb) [prescribing information]. Nutley, NJ: Eisai and Biogen; August 2025.
14. Petersen RC. Mild cognitive impairment: Epidemiology, pathology, and clinical assessment. UpToDate Web site. Updated May 28, 2024. Accessed July 12, 2024.
15. Reardon S. FDA approves Alzheimer's drug lecanemab amid safety concerns. *Nature*. 2023;613(7943):227-228.
16. Sevigny J, Chiao P, Bussière T, et al. The antibody aducanumab reduces Aβ plaques in Alzheimer's disease. *Nature*. 2016;537:50-56.

18. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer disease with lecanemab, anti-Aβ protofibril antibody. *Alzheimers Res Ther*. 2021;13(80):1-14.
19. Swanson CJ, Zhang Y, Dhadda S, Wang J, Kaplow J, Lai RYK, 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 Apr 17;13(1):80. doi: 10.1186/s13195-021-00813-8.
20. VanDyck CH, Swanson CJ, Aisen P, Bateman RJ, Chen C, Gee M, et al. Lecanemab in Early Alzheimer's Disease. N Engl J Med. 2023 Jan 5;388(1):9-21. doi: 10.1056/NEJMoa2212948. Epub 2022 Nov 29.
21. Wang J, Logovinskkiy V, Hendrix SB, et al. ADCOMS: a composite clinical outcome for prodromal Alzheimer's disease trials. *J Neurol Neurosurg Psychiatry*. 2016;87:993-999.
22. Withington CG, Turner RS. Amyloid-related imaging abnormalities with anti-amyloid antibodies for the treatment of dementia due to Alzheimer's disease. *Front Neurol*. 2022;13:1-7.

Review History

11/12/2025 – Reviewed at November P&T. Effective 03/01/2026.
01/14/2026 – Reviewed and updated at February P&T. Updated initial criteria to include diagnoses. Updated requirement of no concomitant use with the IV formulation from documentation to attestation. Effective 03/01/2026.