Mass General Brigham
Health Plan

Alzheimer's Agents – Anti-Amyloid Antibodies
Leqembi (lecanemab-irmb)
Effective 12/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Leqembi is amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. The medication is monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. Leqembi reduces amyloid beta plaques, the accumulation of which is a defining pathophysiological feature of Alzheimer disease.

Coverage Guidelines
Authorization may be granted for members new to Mass General Brigham Health Plan 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
Leqembi
Authorization may be granted for members meeting ALL the following criteria:

1. Member has ONE of the following:
    a. Mild cognitive impairment (MCI)
    b. Mild dementia associated with Alzheimer's disease (AD)
2. Prescriber is a neurologist or geriatrics specialist consult notes from a neurologist or geriatrics specialist are provided
3. Medical records documenting Apolipoprotein E ε4 genetic testing to evaluate risk of amyloid related imaging abnormalities (ARIA)
4. Medical records documenting confirmed evidence of clinically significant AD neuropathology based on ONE of the following:
    a. Amyloid positron emission tomography (PET)
    b. Cerebral spinal fluid (CSF) biomarkers
5. Member has had a brain magnetic resonance imaging (MRI) within the last 12 months
6. Medical records documenting baseline (within the last 3 months) cognitive function based on ONE of the following objective assessments:
    a. Mini Mental State Exam (MMSE) score of ≥ 22

b. Montreal Cognitive Assessment (MoCA) score of ≥15
c. Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1

7. Dosing is appropriate
8. Member does not have any contraindications (see Appendix)

Continuation of Therapy

Authorization may be granted for members who achieve or maintain a positive clinical response and when ALL the following is met:

1. Dosing is appropriate
2. Provider attestation that MRI monitoring has been completed before the fifth, seventh, and fourteenth infusions, again after one year of treatment (i.e., prior to the 26th infusion) and then periodically guided by patient symptoms and prior MRI findings in accordance with the FDA approved label
3. Medical charts showing clinical benefit or delay in disease progression as documented by ONE of the following (within the last 3 months):
    a. Mini Mental State Exam (MMSE) score of ≥ 22
    b. Montreal Cognitive Assessment (MoCA) score of ≥15
    c. Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1
4. Member does not have any contraindications (see Appendix)

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months.

Appendix

Contraindications to Leqembi:

1. Any medical or neurological condition, other than AD, that might be a contributing cause of the individual's cognitive impairment
2. History of TIA, stroke, or seizures in the past year
3. Contraindications to brain MRI scanning (e.g., non-MRI compatible implants)
4. Evidence of other clinically significant lesions on brain MRI that indicate another cause of the individual's cognitive impairment
5. Uncontrolled bleeding disorder (including platelet count <50,000 or INR >1.5)
6. Use of anticoagulants and/or antiplatelet medications or concomitant use has been evaluated by physician
7. Any uncontrolled immunological disease or immunological disease requiring treatment with immunoglobulins, systemic monoclonal antibodies, systemic immunosuppressants, or plasmapheresis

References

1. Leqembi® [package insert]. Nutley (NJ): Eisai, Inc.; 2023 Jan.
2. CMS Finalizes Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease [press release on the internet]. Baltimore (MD): Centers for Medicare and Medicaid Services; 2022 Apr 7 [cited 2023 Jun 16]. Available from: https://www.cms.gov/newsroom/press-releases/cms-finalizes-medicare-coverage-policy-monoclonal-antibodies-directed-against-amyloid-treatment.
3. CMS Statement on FDA Accelerated Approval of Lecanemab [press release on the internet]. Baltimore (MD): Centers for Medicare and Medicaid Services; 2023 Jan 6 [cited 2023 Jun 16]. Available from: https://www.cms.gov/newsroom/press-releases/cms-statement-fda-accelerated-approval-lecanemab.

4. FDA Advisory Committee Votes Unanimously to Confirm the Clinical Benefit of LEQEMBI® (lecanemab-irmb) for the Treatment of Alzheimer's Disease Lecanemab [press release on the internet]. Cambridge (MA): Biogen, Inc.; 2023 June 9 [cited 2023 Jun 16]. Available from: https://investors.biogen.com/news-releases/news-release-details/fda-advisory-committee-votes-unanimously-confirm-clinical.
5. Kimball S. FDA advisors endorse Alzheimer's treatment Leqembi paving way for full approval this summer. CNBC; June 9 2023 [cited 2023 Jun 16]. Available from: https://www.cnbc.com/2023/06/09/fda-advisors-review-alzheimers-drug-leqembi-for-full-approval.html.
6. 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.
7. 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.
8. 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.

Review History
10/11/2023 - Reviewed at October P&T, Effective 12/1/23