Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Leqembi™ (lecanemab)

Effective: July 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

An estimated 6.7 million Americans aged 65 and older are living with Alzheimer's in 2023. Seventy-three percent are age 75 or older. Alzheimer's disease (AD) is the most common cause of dementia, accounting for an estimated 60% to 80% of cases. It is a progressive, irreversible neurodegenerative disease associated with cognitive, functional, and behavioral impairments. It is thought to be caused by the progressive accumulation of amyloid beta (Aβ) plaques and neurofibrillary tangles (NFTs) formed by aggregated tau protein. The average life expectancy after a diagnosis of AD has been reported to be between 8 and 10 years, but this may vary based on disease progression. Survival also relates to age at onset of symptoms.

Medications currently available for management of AD/dementia include potentially disease-modifying agents (lecanemab, donanemab), agents for cognitive symptoms (cholinesterase inhibitors and glutamate regulators), and agents for behavioral and psychological symptoms of dementia (BPSD)/Neuropsychiatric symptoms (NPS) (antipsychotics, etc.). The AD/dementia pipeline includes agents being developed in each of these aforementioned categories.

Currently, Leqembi is one of two disease-modifying agents (both amyloid-targeting monoclonal antibodies) approved by the FDA for early Alzheimer's Disease.

On January 6, 2023, Leqembi received accelerated approval by the FDA. Leqembi is a humanized IgG1 monoclonal antibody that binds to soluble amyloid beta aggregates for the treatment of mild cognitive impairment (MCI) due to AD and mild AD. On July 6, 2023, the accelerated approval of Leqembi was converted to a traditional approval, which opened the door to broader coverage of the agent. Approval based on positive results from the Phase 3 CLARITY AD trial, achieving both the primary endpoint (Clinical Dementia Rating-Sum of Boxes [CDR-SB]) and all key secondary endpoints. CDR-SB scores demonstrated a 27% reduction in clinical decline compared with placebo at 18 months; there is debate over the clinical significance of the CLARITY results.

The recommended dosage of LEQEMBI is 10 mg/kg administered intravenously once every two weeks to eligible patients with confirmed presence of Aβ pathology prior to initiating treatment. Enhanced clinical vigilance for amyloid-related imaging abnormalities (ARIA) is recommended during the first 14 weeks of treatment with LEQEMBI. Baseline, recent (within one year) brain MRI prior to initiating treatment with LEQEMBI and periodic monitoring with MRI prior to the 5th, 7th, and 14th infusions should be obtained.

CMS announced its final Medicare national coverage determination (NCD) that covers FDA approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD) when furnished in accordance to the Coverage Criteria specified under coverage with evidence development (CED) for patients who have a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD.

Food and Drug Administration (FDA) Approved Indications:

Leqembi (lecanemab) is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Leqembi should be initiated in patients with Alzheimer's disease who have:

- Mild cognitive impairment, or
- Mild dementia stage of disease

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Leqembi, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with Leqembi.

Patients who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including Leqembi, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed, they can still be treated with Leqembi; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA.

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Leqembi for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria:

1. Documentation is submitted that confirms diagnosed of mild cognitive impairment or early dementia caused by Alzheimer's disease

AND

2. Leqembi must be prescribed by a qualified physician participating in a CMS-approved Monoclonal Antibodies Against Amyloid for the Treatment of Alzheimer's Disease CED Study registry, with an appropriate clinical team and follow up care

Note- *registries are common tools in clinical settings that have successfully gathered information on patient outcomes for decades. There is strong precedent for using registries to gather more information on a newly approved treatment*

AND

3. Member has confirmation of the presence of amyloid beta pathology prior to initiating treatment

Reauthorization Criteria:

The Plan may authorize coverage of Leqembi for Members when all of the following criteria are met:

1. The member continues to participate in a CMS-approved Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry with an appropriate clinical team and follow-up care
2. Documentation the member has had follow up MRI's

Limitations

- Leqembi will not be covered for an earlier or later stages of Alzheimer's Disease
- Initial authorization of Leqembi is limited to a total of 6 months if initial authorization criteria are met
- Reauthorization for Leqembi may be granted for a period of up to 6 months when reauthorization criteria are met

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0174	Lecanemab-irmb, for intravenous injection, 1 mg

References:

1. Leqembi (lecanemab) [package insert]. Nutley, NJ; Eisai Inc.; January 2023.
2. CMS announces plan to ensure availability of new Alzheimer's drugs. 2023, June 1. CMS Center for Medicare and Medicaid Services. https://www.cms.gov/newsroom/press-releases/cms-announces-plan-ensure-availability-new-alzheimers-drugs. Accessed June 12, 2023.
3. Clinical Guidelines Clinical Diagnosis of Alzheimer's Disease, Lancet Neurol, 2021 . Accessed November 9. 2023. https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(21)00066-1/fulltext
4. American Academy of Neurology Practice Guideline Update Summary: Mild Cognitive Impairment, Neurology, 2018. Accessed November 9, 2023. https://www.aan.com/Guidelines/home/GuidelineDetail/881.
5. Leqembi Prescribing Information. Accessed November 9, 2023. https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf?hash=77aa4a86-b786-457a-b894-01de37199024.

6. National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (200.3 – Version 1).

Approval And Revision History

June 21, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

July 11, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T) effective July 11, 2023

Subsequent endorsement date(s) and changes made:

- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- April 2024: Administrative Update: Added J Code J0174 to Medical Necessity Guideline.
- December 2024: Reviewed by Pharmacy and Therapeutics Committee (P&T) effective Jan 1, 2025
- December 2024: Joint Medical Policy and Health Care Services UM Committee review effective Jan 1, 2025
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)
- April 2026: Administrative update: Updated description for J code, J0174, effective 4/1/26.
- June 2026: Joint Medical Policy and Health Care Services UM Committee review; removed required attestation that the provider has discussed performing genotype testing for apolipoprotein E ε4 (ApoE ε4) status prior to initiation of treatment (effective 7/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.