Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Leqembi™ (lecanemab)

Effective: May 12, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ 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

Alzheimer's disease (AD) is a currently irreversible brain disorder that progressively degrades memory, cognitive function, and ability to carry out tasks of daily living. AD is the number one cause of dementia in older Americans, contributing to 60-80% of cases. Over 6 million older Americans are believed to have AD. This prevalence is expected to rise to 14 million by 2060 barring effective interventions (such as lifestyle changes, treatment of risk factors, and possibly combinations of Alzheimer's drugs). AD is the sixth leading cause of death in the United States but may rank from fifth to as high as third (after heart disease and cancer) as a cause of death for older Americans. Women are more likely to have AD than men, although this is in part because women live longer. (AA 2021, NIA 2021, CDC 2021, Rajan 2021, Brookmeyer 2018, 2019.) Most individuals with AD become symptomatic after age 65. Alzheimer's can be fatal anywhere between 2 and 20 years of symptom onset, but 8 years on average (in those with onset before age 75 years). However, pathophysiologic changes in the brain (including amyloid-beta [Aβ] plaques and neurofibrillary tangles of tau) may be evident up to decades before symptoms occur. Among 70-year-olds, 61% of those with AD die within a decade (compared to only 30% of those without AD). However, most persons who have evidence of AD pathology but are asymptomatic will not develop AD dementia during their lifetimes. (Ganguli 2005, Brookmeyer 2018, AA 2021, Dilworth 2008, Sperling 2011, CMS 2013, Jack 2010).

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, the population in which treatment was initiated in clinical trials.

Clinical Guideline Coverage Criteria

Initial Authorization Criteria

The Plan may cover Leqembi (lecanemab) when **ALL** of the following clinical criteria are met:

1. The Member has a diagnosis of Mild Alzheimer's Disease, is in the mild dementia stage of disease, or has Mild Cognitive Impairment (MCI) Due to Alzheimer's disease and meets the NIA-AA core clinical criteria for probable disease confirmed by both of the following:
    a. A global CDR score of 0.5 to 1

    AND

    b. A CDR Memory Box score of 0.5 or greater

    AND

2. At baseline, the Member has a Mini Mental State Examination (MMSE) score greater than or equal to 22 but less than or

equal to 30

AND

3. The Member is between 50 and 90 years of age

AND

4. There is documented evidence of amyloid pathology consistent with AD as evidenced by either one (1) of the following tests:
    a. An Amyloid Positron Emission Tomography (PET) scan

    OR

    b. A lumbar puncture confirming the presence of elevated phosphorylated tau (P-tau) protein and reduced beta amyloid-42 (AB42) or a low AB42/AB40 ratio as determined by the lab assay detected in cerebrospinal fluid (CSF)

AND

5. Before initiating treatment with Leqembi, the member has had a recent brain MRI (within one year) to confirm the absence of pre-existing amyloid related imaging abnormalities (ARIA)

AND

6. Documentation that the member has had genotype testing for apolipoprotein E ε4 (ApoE ε4) status performed prior to initiation of treatment to evaluate risk of amyloid related imaging abnormalities (ARIA)

AND

7. If member is homozygous for the ApoE ε4 gene, documentation that the member has been counseled that they are at increased risk for ARIA and the member and provider has determined that the benefits outweigh the risks

AND

8. Leqembi is being prescribed by a Neurologist, Geriatric Psychiatrist, or Neuropsychiatrist who specializes in the treatment of Alzheimer's Disease

AND

9. The Provider attests that the Member does not have one (1) or more of the following:
    a. Any neurological or other medical condition(s), other than AD, that may significantly contribute to cognitive decline

    OR

    b. Expected death from any cause during the duration of Leqembi treatment

    OR

    c. Any medical condition other than AD that may increase the likelihood of significant adverse events while being treated with Leqembi

    OR

    d. A history of brain hemorrhage, bleeding disorders, cerebrovascular abnormalities, stroke or Transient Ischemic attack (TIA)

    OR

    e. Member currently receiving anticoagulant therapy (e.g. apixaban, dabigatran, enoxaparin, heparin, rivaroxaban, warfarin)

Reauthorization Criteria

1. The Member meets all the initial criteria above for Leqembi therapy

AND

2. One of the following:
    a. If requesting for the first reauthorization, medical records confirm that the Member has undergone MRI testing before the 5th and 7th infusions, and the results indicate there is no evidence of moderate to severe, or clinically relevant ARIA-H that would warrant discontinuation of treatment
    b. If requesting for the second reauthorization, medical records confirm that the Member has undergone MRI testing before the 14th infusion, and the results indicate there is no evidence of moderate to severe, or clinically relevant ARIA-H that would warrant discontinuation of treatment
    c. If requesting for subsequent reauthorization, **BOTH** of the following:
        i. Documentation of change from baseline PET scan or CSF analysis confirming one (1) of the following is obtained at or around 18 months of treatment:
            a. Amyloid PET scan demonstrating a reduction in amyloid plaques from baseline noted by both of the following:
                i. Composite Standard Uptake Value Ratio (SUVR) reduction of at least 0.2 points
                ii. Amyloid PET Centiloid reduction of at least 50%.

OR

b. CSF results demonstrating a reduction in tau pathophysiology and neurodegeneration from baseline as noted by both of the following:
   i. P-Tau reduction of at least 20 pg/mL
   ii. T-Tau reduction of at least 110 pg/mL

AND

ii. Medical records confirm that the Member has undergone MRI testing every 12 months thereafter, and the results indicate there is no evidence of moderate to severe, or clinically relevant ARIA-H that would warrant discontinuation of treatment

Note: Members with mild ARIA on MRI who are asymptomatic may continue dosing

Limitations

- Initial authorization of Leqembi is limited to a total of 6 months if initial authorization criteria are met.
- First reauthorization for Leqembi may be granted for a period of up to 6 months when reauthorization criteria are met.
- Subsequent reauthorization for Leqembi may be granted for a period of up to 12 months when reauthorization criteria are met.
- Members new to the plan stable on Leqembi should be reviewed against Reauthorization Criteria
- The Plan will not cover Leqembi for Members with a brain MRI that shows evidence of severe ARIA-H (see appendix below), evidence of other clinically significant lesions on brain MRI at screening that could indicate a dementia diagnosis other than Alzheimer's disease, or Members with a diagnosis of cerebral amyloid angiopathy
- The Plan will not cover Leqembi for Members at increased risk for intracranial hemorrhage based on members with a brain MRI that shows evidence of acute or sub-acute hemorrhage or prior subarachnoid hemorrhage

Appendix:

Clinical Dementia Rating

CRD 0	No Dementia
CDR 0.5	Questionable Dementia
CRD 1	Mild Cognitive Impairment
CRD 2	Moderate Cognitive Impairment
CRD 3	Severe Cognitive Impairment

Mini Mental Status Exam

Score	**Degree of Impairment**
25-30	Questionably significant
20-25	Mild
10-20	Moderate
0-10	Severe

ARIA MRI Classification Criteria

ARIA Type	**Radiographic Severity**		
	Mild	**Moderate**	**Severe**
ARIA-E	FLAIR hyperintensity confined to sulcus and or cortex/subcortical white matter in one location < 5 cm	FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring < 10 cm	FLAIR hyperintensity measuring > 10 cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted.
ARIA-H microhemorrhage	≤ 4 new incidents microhemorrhages	5 to 9 new incidents microhemorrhages	10 or more new incidents microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	> 2 focal areas of superficial siderosis

HCPCS Codes

The following code(s) require prior authorization:

HCPCS Codes	Description
J0174	Injection, lecanemab-irmb, 1 mg

References:

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2. Lecanemab (Leqembi) for Alzheimer Disease- Emerging Technology Report Jan 09, 2023. Hayes. Accessed online January 10, 2023 at file:///D:/Point%2032%20Folders/Medical%20Benefit%20Drugs/2023%20Updates/Leqembi/Lecanemab%20Hayes%201.10.2023.pdf.
3. Leqembi (lecanemab) [package insert]. Nutley, NJ; Eisai Inc.; November 2024.
4. Lecanemab – Updated clinical data indicate a modest clinical effect on the disease. OptumRx Clinical Updates. OptumRx Clinical News. December 2, 2022.
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7. 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. Alzheimer's Dement. 2011;7(3):263-269.
8. 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. Alzheimer's Dement. 2011;7(3):270-279.
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10. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975;12(3):189-198.
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12. Mendez MF, Mental status scales to evaluate cognition. UpToDate, updated April 16, 2019. http.uptodate.com. Accessed January 4, 2023.
13. C.H. van Dyck. Lecanemab in Early Alzheimer's Disease. *NEJM*. This article was published on November 29, 2022, at NEJM.org. DOI: 10.1056/NEJMoa2212948.
14. Wolk DA, Dickerson BC. Clinical features and diagnosis of Alzheimer disease. UpToDate, updated December 11, 2020. http://www.uptodate.com. Accessed January 4, 2023.

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
- April 2024: Administrative Update: Added J code J0174 to Medical Necessity Guideline.
- July 9, 2024: Effective August 14, 2024, removed Tufts Health Together from Medical Necessity Guideline. Coverage for Tufts Health Together falls under Unified Medical Policies Medical Necessity Guideline (effective 8/14/24). Removed the Limitation The Plan will not cover Leqembi for any indication that has not been approved by the Food and Drug Administration (FDA). Administrative updates to overview section and minor wording updates.
- November 12, 2024: Effective December 1, 2024, clarified reauthorization criteria to indicate that MRI testing prior to the 14th infusion is applicable to second reauthorization. First reauthorization may be granted for up to 6 months, and update that subsequent reauthorization may be granted for up to 12 months.
- January 14, 2025: Effective April 1, 2025, added criterion for apolipoprotein E ε4 (ApoE ε4) status prior to initiation of treatment.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- May 12, 2026: No changes, administrative update to template to remove CareLink from the Medical Necessity Guideline template. Administrative update from "Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership

Plans" to "Tufts Health Together- MassHealth Accountable Care Partnership Plans."

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.