

Effective: August 14, 2024

<b>Prior Authorization Required</b> If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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**Applies to:**

**Commercial Products**

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

CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

- ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
- ☐ Tufts Health Together – MassHealth MCO Plan and 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**

- ☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
- ☐ 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.

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## 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. Leqembi is being prescribed by a Neurologist, Geriatric Psychiatrist, or Neuropsychiatrist who specializes in the treatment of Alzheimer's Disease
- AND**
7. 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. Medical records confirm that the Member has undergone MRI testing before the 5<sup>th</sup>, 7<sup>th</sup>, and 14<sup>th</sup> infusions, and 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

**AND**

3. For Members who have been receiving the medication for more than 12 months, 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

**AND**

- 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

**AND**

- ii. T-Tau reduction of at least 110 pg/mL

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## Limitations

- 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.
- 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

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## 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
<b>ARIA-E</b>	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.
<b>ARIA-H microhemorrhage</b>	≤ 4 new incidents microhemorrhages	5 to 9 new incidents microhemorrhages	10 or more new incidents microhemorrhages
<b>ARIA-H superficial siderosis</b>	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	> 2 focal areas of superficial siderosis

## Codes

The following code(s) require prior authorization:

## HCPCS Codes

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

## References:

1. Beta-Amyloid Antibodies for Early Alzheimer's Disease. ICER Evidence Report. Institute for Clinical and Economic Review (ICER). December 22, 2022. Accessed online January 10, 2023 at [https://icer.org/wp-content/uploads/2021/12/ICER\\_Alzheimers-Disease\\_Draft-Report\\_12222022.pdf](https://icer.org/wp-content/uploads/2021/12/ICER_Alzheimers-Disease_Draft-Report_12222022.pdf).
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.; July 2023.
4. Lecanemab – Updated clinical data indicate a modest clinical effect on the disease. OptumRx Clinical Updates. OptumRx Clinical News. December 2, 2022.
5. Alzheimer's Disease pipeline update- Lecanemab. OptumRx Clinical Updates. OptumRx Clinical News. September 27, 2022.
6. Lecanemab for Alzheimer's disease: tempering hype and hope. The Lancet. December 3, 2022, vol 400.
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.
9. O'Bryant SE, Waring SC, Cullum CM, et al. Staging Dementia Using Clinical Dementia Rating Scale Sum of Boxes Scores: A Texas Alzheimer's Research Consortium Study. *Arch Neurol*. 2008;65(8):1091–1095.
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.
11. CDR Dementia Staging Instrument. Knight Alzheimer Disease Research Center. <https://knightadrc.wustl.edu/cdr/cdr.htm>. Accessed: January 4, 2023.
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

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## 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.

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## 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.