Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Leqembi™ (lecanemab)

Effective: July 11, 2023

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
CareLink℠ – 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 Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify 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

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 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 the presence of amyloid beta pathology prior to initiating treatment

AND

4. Member has obtained a recent (within one year) brain MRI prior to initiating treatment to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA)

Reauthorization Criteria

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

1. Member has obtained an MRI prior to the 5th, 7th, and 14th infusions. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms

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
	None

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.

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

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.