CarePartners of Connecticut MEDICARE ADVANTAGE

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:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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, aducanumab), 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

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
J0174	Injection, lecanemab-irmb, 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. Leqembi Prescribing Information. Accessed November 9, 2023. https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf?hash=77aa4a86-b786-457a-b894-01de37199024.
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. 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

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:

- 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

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.