Medical Policy:

Leqembi™ (lecanemab-irmb) Intravenous- MEDICAID ONLY

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.421	September 12, 2024	September 12, 2024

Definitions

Leqembi is indicated for the treatment of Alzheimer's disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

Length of Authorization

Coverage will be provided for 6 months and may be renewed for Medicaid members.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

1200 billable units (1200 mg) every 14 days

Guideline

I. Initial Criteria

Coverage is provided in the following conditions:

1. Patient is at least 18 years of age; **AND**
2. Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Mini-Mental Status Exam [MMSE], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating- Sum of Boxes [CDR-SB], etc.); **AND**
3. Patient does not have any of the following risk factors for intracerebral hemorrhage: findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage > 1 cm in greatest diameter, > 4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions(aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage; **AND**
4. Patients receiving antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) prior to starting treatment with Leqembi have been on a stable dose for at least 4 weeks; **AND**
    A. Patient has been tested prior to treatment to assess apolipoprotein E ε4 (ApoE ε4)status (e.g., homozygote, heterozygote, or noncarrier) and the prescriber has informed the patient that those who are homozygotes have a higher incidence of developing ARIA; **OR**
    B. Genotype testing has not been performed and the prescriber has informed the patient that it cannot be determined if they are ApoE ε4 homozygotes and, therefore, if they are at higher risk for developing ARIA; **AND**
5. Must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
6. Patient has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment and periodically throughout therapy (*see prescribing information for schedule of MRI scans*); **AND**
7. Patient has not had a stroke or transient ischemic attack (TIA) or seizures in the past 12 months; **AND**
8. Patient does not have a clinically significant and unstable psychiatric illness in the past 6 months; **AND**
9. Patient does not have a history of alcohol or substance abuse in the preceding year; **AND**

Alzheimer's Disease (AD) †

A. Patient has mild cognitive impairment (MCI) due to AD or has mild Alzheimer's dementia (there is insufficient evidence in moderate or severe AD) as evidenced by ALL of the following:
    i. Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0
    ii. Memory Box Score of at least 0.5
    iii. Objective evidence of cognitive impairment at screening
    iv. MMSE score between 22-30, inclusive
    v. Positron Emission Tomography (PET) scan or CSF assessment of Aß (1-42) is positive for amyloid beta plaque

B. Other conditions mimicking, but of non-Alzheimer's Dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus, etc.)

II. Renewal Criteria

Coverage may be renewed based upon the following criteria:

1. Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: amyloid related imaging abnormalities-edema (ARIA-E) and -hemosiderin deposition (ARIA-H), intracerebral hemorrhage, severe hypersensitivity reactions, etc.; **AND**
3. Patient has responded to therapy compared to pretreatment baseline as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in one or more of the following (not all-inclusive): ADAS-Cog 13; ADCS-ADL-MCI; MMSE; CDR-SB, etc.; **AND**

4. Patient has not progressed to moderate or severe AD; **AND**
5. Patient has received a pre- 5th, 7th, AND 14th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities-edema (ARIA-E) and Amyloid Related Imaging Abnormalities-hemosiderin (ARIA-H) microhemorrhages; **AND**

ARIA-E §

A. Patient is asymptomatic or mildly symptomatic* with mild radiographic severity** on MRI; **OR**
B. Patient is asymptomatic or mildly symptomatic* with moderate to severe radiographic severity** on MRI **AND** administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve; **OR**
C. Patient has moderate to severe symptoms* with mild to severe radiographic severity** on MRI **AND** administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve

ARIA-H §

A. Patient is asymptomatic with mild radiographic severity** on MRI; **OR**
B. Patient is asymptomatic with moderate radiographic severity** on MRI **AND** administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; **OR**
C. Patient is symptomatic with mild to moderate radiographic severity** on MRI **AND** administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; **OR**
D. Patient has severe radiographic severity** on MRI AND administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve

§ Clinical judgment will be used in considering whether to continue treatment or permanently discontinue. In patients who develop intracerebral hemorrhage greater than 1 cm in diameter during treatment from Leqembi, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification.

† FDA Approved Indication(s)

Clinical Symptom Severity*		
Mild	**Moderate**	**Severe**
Discomfort noticed, but no disruption of normal daily activity	Discomfort sufficient to reduce or affect normal daily activity	Incapacitating, with inability to work or to perform normal daily activity

ARIA Type[1]	Radiographic Severity **		
	Mild	**Moderate**	**Severe**
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortex white matter in one location < 5 cm	FLAIR hyperintensity 5 to 10 cm in single greatest dimension, or more than 1 site of involvement, each measuring < 10 cm	FLAIR hyperintensity measuring > 10 cm with associated gyral swelling and sulcal effacement. One or more separate/independent sites of involvement may be noted.
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	> 2 focal areas of superficial siderosis

Applicable Procedure Codes

Code	Description
J0174	Injection, lecanemab-irmb, 1 mg

Applicable NDCs

Code	Description
62856-0212-01	Leqembi 200 mg/2mL
62856-0215-01	Leqembi 500 mg/5mL

ICD-10 Diagnoses

Code	Description
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	9/12/2024	New Policy

References

1. Leqembi [package insert]. Nutley, NJ; Esai, Inc; January 2023. Accessed May 2023