Medical Policy:

Leqembi™ (lecanemab-irmb) Intravenous- MEDICAID ONLY

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.421	March 20, 2025	September 12, 2024

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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], Montreal Cognitive Assessment (MoCA) 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**
10. Will not be used concurrently with other anti-amyloid immunotherapies (i.e., donanemab, aducanumab, etc.); **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 **BOTH** of the following:
    i. Positron Emission Tomography (PET) scan positive for amyloid beta plaque or CSF assessment positive for hybrid ratios of Aβ 42/40, CSF p-tau 181/Aβ 42, or CSF t-tau/Aβ 42; **AND**
    ii. One of the following*:
        a. Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0 with Memory Box Score of at least 0.5; **OR**
        b. MMSE score between 20-28, inclusive; **OR**
        c. Montreal Cognitive Assessment (MoCA) score 18-25, inclusive; **AND**

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**

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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

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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	03/20/2025	Annual Review: Added: “Montreal Cognitive Assessment (MoCA)” as a baseline assessment tool option. Added: “Will not be used concurrently with other anti-amyloid immunotherapies (i.e., donanemab, aducanumab, etc.); AND” Alzheimer’s Disease (AD) † In the following statement: 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 Changed “ALL” to “BOTH” of the following: Removed the following (some of which was reworded):”Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0 Memory Box Score of at least 0.5 Objective evidence of cognitive impairment at screening MMSE score between 22-30, inclusive Positron Emission Tomography (PET) scan or CSF assessment of Aß (1-42) is positive for amyloid beta plaque” Updated with:”Positron Emission Tomography (PET) scan positive for amyloid beta plaque or CSF assessment positive for hybrid ratios of Aβ 42/40, CSF p-tau 181/Aβ 42, or CSF t-tau/Aβ 42; AND One of the following*: Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0 with Memory Box Score of at least 0.5; OR MMSE score between 20-28, inclusive; OR Montreal Cognitive Assessment (MoCA) score 18-25, inclusive; AND”
EmblemHealth & ConnectiCare	9/12/2024	New Policy

References

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

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