

Medical Policy:

Leqembi™ (lecanemab-irmb) intravenous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.381	February 5, 2024	March 30, 2023

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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. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.

Policy Statement

For Commercial and Medicaid ONLY: EmblemHealth will not cover Leqembi due to lack of conclusive evidence confirming clinical efficacy.

For Medicare: Coverage guidance is set forth in National Coverage Determinations (NCD) and Local Coverage Determinations (LCD).

Applicable Procedure Codes

Code	Description
J0174	Leqembi 200mg/2mL, 500mg/5mL

Applicable NDCs

Code	Description
62856-0212-01	Leqembi 100mg/mL intravenous 2mL
62856-0215-01	Leqembi 100mg/mL intravenous 5mL

ICD-10 Diagnoses

Code	Description
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	2/5/2024	Annual Review: No changes
EmblemHealth & ConnectiCare	8/21/2023	<u>Policy Statement:</u> Updated Statement to add "For Commercial and Medicaid ONLY": EmblemHealth will not cover Leqembi due to lack of conclusive evidence confirming clinical efficacy. Added "For Medicare: Coverage guidance is set forth in National Coverage Determinations (NCD) and Local Coverage Determinations (LCD)."
EmblemHealth & ConnectiCare	03/30/2023	New Policy

References

1. Leqembi™ intravenous infusion [prescribing information]. Nutley, NJ: Eisai; January 2023.
2. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody. *Alzheimers Res Ther.* 2021;13(1):80.
3. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med.* 2023;388(1):9-21.
4. Andrews JS, Desai U, Kirson NY, et al. Disease severity and minimal clinically important differences in clinical outcome assessments for Alzheimer's disease clinical trials. *Alzheimers Dement.* 2019;5:354-363.