Medical Policy

Leqembi™ (lecanemab-irmb)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-133
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Leqembi™ (lecanemab-irmb) therapy.

POLICY

Leqembi™ (lecanemab-irmb) is not considered medically necessary due to insufficient evidence of therapeutic value. Lecanemab-irmb does not meet the definition of medical necessity for all indications including, but not limited to, Alzheimer's disease, cognitive impairment due to Alzheimer's disease, Alzheimer's disease related dementia, as a clinical benefit has not been established.

LIMITATIONS/EXCLUSIONS

1. Leqembi is considered experimental and investigational for all indications and is therefore not covered.

2. Medicare benefit

    a. Coverage of the Leqembi is contingent upon patient enrollment in a qualifying clinical trial (FDA-approved randomized controlled trial, CMS approved study, or study supported by the NIH).
    b. Any other use is considered investigational/experimental for all indications due to insufficient evidence of a clinical benefit and is NOT covered.

BACKGROUND

Lecanemab-irmb is a recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. Lecanemab-irmb is indicated for the treatment of Alzheimer's disease in those with mild cognitive impairment or mild dementia as studied in clinical trials.

This indication was approved under an accelerated approval based on a reduction in accumulation of amyloid beta plaques observed in patients treated with lecanemab-irmb. The relationship between clearance of beta amyloid in the brain and clinical improvement has not been demonstrated. Use of lecanemab-irmb may result in ARIA, including bleeding into brain tissue.

DEFINITIONS

1. LEQEMBI (lecanemab-irmb) injection is a preservative-free, sterile, clear to opalescent, and colorless to pale yellow solution for intravenous use by infusion after dilution. LEQEMBI is supplied one vial per carton as follows:
    a. 500mg/5 mL (100mg/mL) in a single dose vial – NDC 62856-0215-01
    b. 200mg/2 mL (100mg/mL) in a single dose vial – NDC 62856-0212-01

CODING

Applicable NDC Codes	
62856-0215-01	LEQEMBI (lecanemab-irmb) injection 500mg/5 mL (100mg/mL) single-dose vial
62856-0212-01	LEQEMBI (lecanemab-irmb) injection 200mg/2 mL (100mg/mL) single-dose vial

Applicable Procedure Code	
J3590	Unclassified biologics (When utilized for Le)

Applicable ICD-10 Codes	
G30	Alzheimer's disease
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

EVIDENCE BASED REFERENCES

1. Product Information: LEQEMBI(TM) intravenous injection, aducanumab-avwa intravenous injection. Biogen, Inc (per FDA), Cambridge, MA, 2021.
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. Alzheimer's Research and Therapy 2021;13:80. DOI: 10.1186/s13195-021-00813-8.
3. NCA - Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N) - Decision Memo (cms.gov)

POLICY HISTORY

Original Effective Date	2/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023 – New Policy
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024