MEDICAL MUTUAL®

Drug Policy

Policy:	**251001**	**Initial Effective Date: 10/16/2025**
Code(s):	**HCPCS J3590, C9399**	**Annual Review Date: New effective policy**
SUBJECT:	**Leqembi IQLIK (lecanemab-irmb) subcutaneous**	**Last Revised Date: 10/16/2025**

Subject to: ☐Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

I. Length of Authorization

- Initial: Not applicable to the subcutaneous formulation. Member must receive at least 18 months (545 days) of treatment with the intravenous (IV) formulation prior being eligible for treatment with the subcutaneous (SQ) formulation *[see Leqembi IV policy – Document Number:24201]*.
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

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

- 360 mg once weekly

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria [1,4-6]

- Must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
- Member 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**
- Will not be used concurrently with other anti-amyloid immunotherapies (i.e., donanemab, lecanemab IV*, etc.) *[*Note: Excludes use during switch therapy with lecanemab IV]*; **AND**

Alzheimer's Disease (AD) † [1]

- Member has received at least 18 months of treatment with the IV formulation; **AND**
- Member has shown a beneficial disease response and/or no worsening of disease with an absence of unacceptable toxicity to the IV doses

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1,4-6]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- 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, hypersensitivity reactions including angioedema, bronchospasm, and, anaphylaxis, infusion-related reactions, etc.; **AND**
- Member 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 13/14; ADCS-ADL-MCI; MMSE; CDR-SB, MoCA, etc.; **AND**
- Member has not progressed to moderate or severe AD; **AND**
- Member has received a pre- 3rd, 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 §

- Member is asymptomatic or mildly symptomatic***** with mild radiographic severity****** on MRI; **OR**
- Member 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**
- Member 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 §

- Member is asymptomatic with mild radiographic severity****** on MRI; **OR**

- Member is asymptomatic with moderate radiographic severity** on MRI AND administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; **OR**
- Member 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**
- Member has severe radiographic severity** on MRI AND administration will be suspended until MRI demonstrates radiographic stabilization and symptoms, if present, resolve

¥ Note: In members who have received 18 months of treatment with Leqembi IV, a transition to maintenance dosage regimen may be considered, which can be administered by either intravenous infusion or subcutaneous injection (Refer the Leqembi IV policy – Document Number: IC-0694 and to Section V below).

§ Clinical judgment will be used in considering whether to continue treatment or permanently discontinue. In members 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.

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

V. Dosage/Administration [1]

Indication	Dose

Alzheimer's Disease (AD)	**Maintenance Dosage**:** Administer Leqembi IQLIK 360 mg as a SQ injection once weekly. *****NOTE:*** • *After 18 months, the intravenous starting dosage of 10 mg/kg every 2 weeks may be continued or a transition to maintenance dosage regimen may be considered, which can be administered by either intravenous infusion or subcutaneous injection (Refer to the Leqembi IV policy – Document Number: IC-0694 for criteria for intravenous use).* • *If transitioning from starting dosage to a maintenance dosage regimen, administer the first maintenance dose two weeks after the last starting dose.* • *Members and/or caregivers are to self-administer Leqembi IQLIK after receiving instruction on how to properly administer the subcutaneous injection.*
– *Obtain an MRI prior to the 3rd, 5th, 7th, and 14th infusions. If a member experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.* – *Recommendations for dosing in members with ARIA-E depend on clinical symptoms and radiographic severity. Recommendations for dosing in members with ARIA-H depend on the type of ARIA-H and radiographic severity. Use clinical judgment in considering whether to continue dosing in members with recurrent ARIA-E.* – *If a starting dosage or maintenance dosage infusion is missed, administer the next dose as soon as possible.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals

NDC:

- Leqembi 360 mg/1.8 mL (200 mg/mL) single-dose prefilled autoinjector: 62856-0220-xx

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist
Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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
G31.84	Mild cognitive impairment of uncertain or unknown etiology

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT,	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.
