Leqembi® (lecanemab-irmb)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

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

- 1200 billable units (1200 mg) every 14 days

III. Initial Approval Criteria [1,4-6,9]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing at least ONE objective measure/tool (i.e., Mini-Mental Status Exam [MMSE], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13/14], 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**
- 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**
- 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**
    - 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**

- 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**

Universal Criteria [1]

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

Alzheimer's Disease (AD) † [1,2,4-6,11,14]

- Patient has a diagnosis of mild cognitive impairment (MCI) due to AD or has mild Alzheimer's dementia (there is insufficient evidence in moderate or severe AD) AND both of the following:
  - 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**
- 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.)

****** Note: the aforementioned cognitive tests are typically the most commonly used but do NOT represent an exhaustive list. Use of alternative cognitive assessment tests not listed will be reviewed on a case-by-case basis.*

† 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:

- Patient 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**

- 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 13/14; ADCS-ADL-MCI; MMSE; CDR-SB, MoCA, etc.; **AND**
- Patient has not progressed to moderate or severe AD; **AND**
- Patient 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 §

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

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

¥ Note: In patients who have received 18 months of treatment with Leqembi IV, the 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 the Leqembi SQ policy – Document Number: IC-0817 and to Section V below).

§ 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.

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)	**Starting Dosage**:** Administer Leqembi 10 mg/kg as an intravenous (IV) infusion over approximately one hour, once every two weeks. **Maintenance Dosage**:** Administer Leqembi 10 mg/kg as an intravenous (IV) infusion over approximately one hour, once every four weeks ***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 SQ policy – Document Number: IC-0817 for criteria for subcutaneous use).* • *If transitioning from starting dosage to a maintenance dosage regimen, administer the first maintenance dose two weeks after the last starting dose.*
– *Obtain an MRI prior to the 3rd, 5th, 7th, and 14th infusions. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.* – *Recommendations for dosing in patients with ARIA-E depend on clinical symptoms and radiographic severity Recommendations for dosing in patients with ARIA-H depend on the type of ARIA-H and radiographic severity. Use clinical judgment in considering whether to continue dosing in patients 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:

- J0174 – Injection, lecanemab-irmb, 1mg; 1 billable unit = 1 mg

NDC:

- Leqembi 200 mg/2 mL (100 mg/mL) solution in a single-dose vial: 62856-0212-xx
- Leqembi 500 mg/5 mL (100 mg/mL) solution in a single-dose vial: 62856-0215-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, AZ	Noridian Healthcare Solutions, LLC
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 Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC