Leqembi® (lecanemab-irmb)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- 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]:

- 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:

- Member 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**
- Member 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**
- Members 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**
    - Member 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 member 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 member 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**
- 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 SQ*, etc.) *[*Note: Excludes use during switch therapy with lecanemab SQ]*; **AND**

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

- Member 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:

- 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 an MRI after 1 month (e.g., prior to the 3rd dose), 2 months, 3 months, and 6 months of treatment 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, the starting dosage of 10 mg/kg every 2 weeks may be continued or a transition to maintenance dosage regimen may be considered (Refer 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 stabilization 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 IV infusion over approximately one hour, once every four weeks ***NOTE:*** • After 18 months, the IV starting dosage of 10 mg/kg every 2 weeks may be continued or a transition to maintenance dosage regimen may be considered. Both the starting and maintenance dosage regimens can be administered by either IV infusion or subcutaneous (SQ) injection. The route of administration can be switched. Please refer to the Prescribing Information when switching the route of administration from IV to SQ or SQ to IV.
– *Obtain MRIs after 1 month (e.g., prior to the 3rd dose), 2 months, 3 months, and 6 months of treatment. If a member experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.* – *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 – Lecanemab-irmb, for intravenous injection, 1mg; 1 billable unit = 1 mg

NDC(s):

- 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

1. Leqembi [package insert]. Nutley, NJ; Esai, Inc.; July 2026. Accessed July 2026.
2. McKhann GM, Knopman DS, Chertklow H, et al. The diagnosis of dementia due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement. 2011;7(3):263. Epub 2011 Apr 21.
3. Sperling RA, Aisen PS, Beckett LA, et al. Toward defining the preclinical stages of Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement. 2011;7(3):280. Epub 2011 Apr 21.
4. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in Early Alzheimer's Disease. N Engl J Med. 2023 Jan 5;388(1):9-21. doi: 10.1056/NEJMoa2212948. Epub 2022 Nov 29. PMID: 36449413.
5. 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.
6. Reish NJ, Jamshidi P, Stamm B, et al. Multiple Cerebral Hemorrhages in a Patient Receiving Lecanemab and Treated with t-PA for Stroke. N Engl J Med 2023 January 4. DOI: 10.1056/NEJMc2215148.
7. O'Bryant SE, Lacritz LH, Hall J, et al. Validation of the new interpretive guidelines for the clinical dementia rating scale sum of boxes score in the national Alzheimer's coordinating center. Arch Neurol. 2010 Jun;67(6):746-9. doi: 10.1001/archneurol.2010.115.
8. Skinner J, Carvalho, JO, Potter GG, et al. The Alzheimer's Disease Assessment Scale-Cognitive-Plus (ADAS-Cog-Plus): an expansion of the ADAS-Cog to improve responsiveness in MCI. Brain Imaging Behav. 2012 Dec;6(4):489-501. doi: 10.1007/s11682-012-9166-3.
9. Lin GA, Whittington MD, Synnott PG, et al. Aducanumab for Alzheimer's Disease: Effectiveness and Value; Final Evidence Report and Meeting Summary. Institute for Clinical and Economic Review, August 5, 2021. https://icer.org/assessment/alzheimers-disease-2021/.
10. Lin GA, Whittington MD, Wright A, et al. Beta-Amyloid Antibodies for Early Alzheimer's Disease: Effectiveness and Value; Draft Evidence Report. Institute for Clinical and Economic Review, December 22, 2022. https://icer.org/assessment/alzheimers-disease-2022/#timeline.
11. Jack CR, Andrews JS, Beach TG, et al. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. *Alzheimer's Dement*. 2024; 20: 5143–5169. https://doi.org/10.1002/alz.13859.
12. Ramanan VK, Armstrong MJ, Choudhury P, et al. Antiamyloid Monoclonal Antibody Therapy for Alzheimer Disease: Emerging Issues in Neurology. Neurology. 2023 Nov 7;101(19):842-852. doi: 10.1212/WNL.0000000000207757. Epub 2023 Jul 26. PMID: 37495380; PMCID: PMC10663011

13. Lin GA, Whittington MD, Wright A, et al. Lecanemab for Early Alzheimer's Disease: Final Evidence Report. Institute for Clinical and Economic Review, April 17, 2023. https://icer.org/wp-content/uploads/2023/04/ICER_Alzheimers-Disease_Final-Report_For-Publication_04172023.pdf
14. Nasreddine ZS, Phillips NA, Bédirian V, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc. 2005 Apr;53(4):695-9. doi: 10.1111/j.1532-5415.2005.53221.x.

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