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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	January 27, 2023
Subject:	Leqembi	**Page:**	1 of 5

Last Review Date: December 12, 2025

Leqembi

Description

Leqembi (lecanemab-irmb) intravenous infusion

Leqembi Iqlik (lecanemab-irmb) subcutaneous injection

Background
Leqembi (lecanemab-irmb) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease (AD). Leqembi reduces amyloid beta plaques (1).

Regulatory Status
FDA-approved indication: Leqembi is an amyloid beta-directed antibody 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 (1).

Leqembi has a boxed warning regarding amyloid related imaging abnormalities (ARIA). A baseline brain magnetic resonance imaging (MRI) should be obtained prior to initiating treatment. An MRI should be obtained prior to the 3rd, 5th, 7th, and 14th infusions (1).

Leqembi carries a warning regarding infusion-related reactions. Consider pre-medication at subsequent dosing with antihistamines, non-steroidal anti-inflammatory drugs, or corticosteroids (1).

In Study 1 (NCT 01767311), the age of patients ranged from 50 to 90 years (1). Clinically, AD can be categorized into two phenotypes based on the ages of onset: early-onset AD (EOAD; <65 years) and late-onset AD (LOAD; >65 years), of which LOAD is the more common form worldwide. The proportion of EOAD in all AD cases is between 5% and 10%. Presenilin 1 (*PSEN1*), presenilin 2 (*PSEN2*), and amyloid precursor protein (*APP*) are mostly associated with autosomal dominant forms of EOAD. Apart from genetic factors, mutations are environmentally related. Genetic–environmental interactions may be caused by variation in the age of onset, neuropathological patterns, and disease duration. To date, more than 200 mutations have been described in *PSEN1* throughout the world, but mutations in *PSEN2* are extremely rare (2).

Do not initiate other anti-amyloid agents or central nervous system agents (e.g., cholinesterase inhibitors or memantine) at the same time as Leqembi. Patients should be on a stable dose for 3 months prior to initiating new therapy (3).

The safety and effectiveness of Leqembi in pediatric patients have not been established (1).

Related policies
Kisunla

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Leqembi may be considered **medically necessary** if the conditions indicated below are met.

Leqembi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Alzheimer's disease (mild cognitive impairment or mild dementia stage of disease)

AND ALL of the following:

1. 50 years of age or older **OR** if less than 50 years of age, patient has a genetic mutation in amyloid precursor protein (APP), presenilin-1 (PSEN1),

or presenilin-2 (PSEN2), or other clinical documentation to support early onset AD
2. Confirmed presence of amyloid pathology by **ONE** of the following:
    a. Amyloid Positron Emission Tomography (PET) scan
    b. Cerebrospinal fluid
    c. Blood/plasma
3. Other causes of dementia (e.g., Lewy body dementia) have been ruled out
4. Patient has mild cognitive impairment or mild AD as confirmed by **ONE** of the following:
    a. Clinical Dementia Rating (CDR®)-Global score of 0.5 or 1.0 (e.g., *https://knightadrc.wustl.edu/professionals-clinicians/cdr-dementia-staging-instrument/*)
    b. Mini-Mental State Examination (MMSE) score of 20 to 30 (e.g., *https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/bc-guidelines/cogimp-smmse.pdf*)
5. A recent (within one year) brain MRI has been obtained or will be obtained prior to initiating treatment with Leqembi
6. Prescriber agrees to monitor for signs and symptoms of amyloid related imaging abnormalities (ARIA) using MRI as clinically appropriate
7. Prescribed by or recommended by a neurologist or a prescriber who specializes in Alzheimer's disease or dementia
8. **NO** neurological or other medical condition, other than AD, that may significantly contribute to cognitive decline
9. **NO** medical conditions, other than AD, likely to increase significant adverse events

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

Alzheimer's disease (mild cognitive impairment or mild dementia stage of disease)

AND ALL of the following:

1. 50 years of age or older **OR** if less than 50 years of age, patient has a genetic mutation in amyloid precursor protein (APP), presenilin-1 (PSEN1), or presenilin-2 (PSEN2), or other clinical documentation to support early onset AD

2. Reduction in brain amyloid beta plaque as confirmed by PET scan
3. Patient continues to have mild cognitive impairment or mild AD as confirmed by stabilization in score in **ONE** of the following:
    a. Clinical Dementia Rating (CDR®)-Global score of 0.5 or 1.0 (e.g., *https://knightadrc.wustl.edu/professionals-clinicians/cdr-dementia-staging-instrument/)*
    b. Mini-Mental State Examination (MMSE) score of 20 to 30 (e.g., *https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/bc-guidelines/cogimp-smmse.pdf*)
4. Prescriber agrees to continue monitoring for signs and symptoms of ARIA using MRI as clinically appropriate
5. **NO** neurological or other medical condition, other than AD, that may significantly contribute to cognitive decline
6. **NO** medical conditions, other than AD, likely to increase significant adverse events

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Leqembi (lecanemab-irmb) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody that reduces amyloid beta plaques in Alzheimer's disease. Patients should have a baseline MRI done prior to initiating therapy with Leqembi and prior to the 3rd, 5th, 7th, and 14th infusions. The safety and effectiveness of Leqembi in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Leqembi while maintaining optimal therapeutic outcomes.

References

1. Leqembi [package Insert]. Nutley, NJ: Eisai Inc.; August 2025.
2. Cai, Y., An, S. S., & Kim, S. (*2015). Mutations in presenilin 2 and its implications in Alzheimer's disease and other dementia-associated disorders*. *Clinical interventions in aging*, *10*, 1163–1172. https://doi.org/10.2147/CIA.S85808.
3. Van Dyck C.H., Swanson C.J., Aisen P., et al (2023). Lecanemab in early Alzheimer's disease. *N. Engl. J. Med.,* 388, 9-21. DOI: 10.1056/NEJMoa2212948.

Policy History

Date	Action
January 2023	Addition to PA
March 2023	Annual review. Per SME, clarified diagnosis to indicate Alzheimer's disease must be in the mild cognitive impairment or mild dementia stage of disease
June 2024	Annual editorial review and reference update
December 2024	Annual review. Per SME, updated requirement for amyloid confirmation by PET scan, cerebrospinal fluid, or blood/plasma; updated CDR link; and changed MMSE score to 20 to 30. Also added statement to regulatory section regarding use with other anti-amyloid agents
June 2025	Annual editorial review and reference update
December 2025	Annual editorial review and reference update. Addition of Leqembi Iqlik subcutaneous dosage form. Per SME, added that the patient could have "mild AD" for the CDR or MMSE scores, added prescriber specialization requirement

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.