

2025 Leqembi FDA Label Addendum

Effective immediately, EviCore will consider MRI Brain without and with contrast (CPT® 70553) or MRI Brain without contrast (CPT® 70551) medically necessary when requested prior to the 3rd dose of Leqembi.

This criteria will also be incorporated into the V1.0.2026 EviCore Head Imaging Guidelines.

On August 28, 2025, the U.S. Food and Drug Administration (FDA) recommended an additional, earlier magnetic resonance imaging (MRI) monitoring prior to the 3rd infusion for individuals with Alzheimer's disease taking Leqembi (lecanemab). The addition of the earlier monitoring is to identify individuals with amyloid-related imaging abnormalities with edema (ARIA-E), which is characterized by brain swelling or fluid buildup. (FDA, 2025)

References:

Eisai Inc. LEQEMBI® (lecanemab-irmb) prescribing information and patient support resources. Published September 2025. <https://www.leqembi.com>

U.S. Food and Drug Administration. FDA to recommend additional, earlier MRI monitoring for patients with Alzheimer's disease taking Leqembi (lecanemab). Published August 28, 2025. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommend-additional-earlier-mri-monitoring-patients-alzheimers-disease-taking-leqembi-lecanemab>