

Which patients might be candidates to refer for lecanemab (Leqembi) evaluation?



Proposed eligibility criteria:

- thorough work-up, including MRI, to look for treatable causes of cognitive impairment
- documented diagnosis of mild cognitive impairment (MCI) or mild Alzheimer's dementia. Not appropriate for moderate-severe Alzheimer's. Criteria include:
 - deficits in memory, behavior, language, and/or executive functioning
 - formal cognitive testing (MMSE \geq 22, MOCA \geq 15)
- elevated brain amyloid levels, measured by baseline PET scan or CSF testing via lumbar puncture
- stable cholinesterase inhibitor or memantine dose, if taking
- presence of a caregiver or family member who can ensure the patient receives the drug, including:
 - intravenous infusions every 2 weeks throughout course of therapy
 - periodic MRIs for monitoring cerebral edema, effusions, or hemorrhage
- understanding of the potential modest benefit balanced against the patient's willingness and capacity for testing, treatment, and financial burden

Patients are not good candidates for lecanemab if they have:

- another cause of cognitive impairment
- history of seizures or stroke/TIAs (transient ischemic attacks) in the past 12 months
- delirium or major psychiatric disease (including untreated severe depression)
- anticoagulant use
- an unstable medical condition
- genetic testing revealing the presence of the *APOE ϵ 4* genotype (especially homozygotes)
- immunologic disease requiring immunoglobulins, monoclonal antibodies, immunosuppressants, or plasmapheresis
- coagulopathy (e.g., platelets $<$ 50,000, or INR $>$ 1.5)

Visit qrc0.de/CMS_registry for the latest on Medicare coverage of lecanemab

This guidance is based on multiple sources: the inclusion and exclusion criteria used in the main lecanemab clinical trial CLARITY-AD,¹ protocols from health care organizations such as the Veterans Affairs Health System,² the recommendations of a group of Alzheimer's Disease specialists,³ the American Geriatrics Society,⁴ and additional expert opinion. These recommendations may change as new information emerges; the final decision about referral should be made by the treating clinician in light of a given patient's specific clinical situation and the most current evidence.

(1) van Dyck CH, et al. Lecanemab in early Alzheimer's Disease. *NEJM*. 2022;388(1):9-21. (2) VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives. Lecanemab-irmb (Leqembi): Criteria for use. 2023; https://www.va.gov/formularyadvisor/DOC_PDF/CFU_Lecanemab-irmb_LEQEMBI_CFU.pdf. (3) Cummings J, et al. Lecanemab: Appropriate Use Recommendations. *J Prev Alzheimers Dis*. 2023;10(3):362-377. (4) American Geriatrics Society. Clinical tools. Lecanemab: What clinicians should know. Nov 16, 2023. <https://geriatricscareonline.org/ProductAbstract/Lecanemab-What-Clinicians-Should-Know/PC0018>.