

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

This guidance is based on multiple sources: the inclusion and exclusion criteria for the main lecanemab clinical trial CLARITY-AD<sup>1</sup>, protocols from health care organizations such as the Veterans Affairs Health System<sup>2</sup>, the recommendations of a group of Alzheimer's Disease specialists<sup>3</sup>, and additional expert opinion. The final decision about referral should be made by the treating physician in light of a given patient's specific clinical situation.

## Proposed eligibility criteria

- documented diagnosis of mild cognitive impairment (MCI) or mild Alzheimer's dementia, but not more severe disease. Criteria include:
  - formal cognitive testing (impairment no worse than MMSE score of 22 or MoCA > 16)
  - deficits in memory, behavior, language, and/or executive functioning that impact daily life
- thorough work-up to establish Alzheimer disease as the likely principal causes of cognitive impairment
- baseline PET scan or CSF testing via lumbar puncture to document elevated brain amyloid levels
- no unstable medical condition
- willingness and ability to undergo serial MRI scans during the first year of therapy
- stable cholinesterase inhibitor or memantine dose for at least 12 weeks (if used)
- 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
- ensuring that the possibility of modest benefit is commensurate with the patient's capacity and willingness to bear the burden of repeated intravenous infusions, testing, and possible economic costs

## Patients are not good candidates for lecanemab if they have:

- a reversible cause of dementia, or a cause of cognitive impairment other than Alzheimer's disease with elevated brain amyloid levels
- transient ischemic attacks (TIA), stroke, or seizures within 12 months
- delirium or major psychiatric disease (including depression, with a GDS score > 8)
- anticoagulant use
- a contradiction to MRI
- an unstable medical condition
- APOE genotyping that reveals e4 homozygosity, which roughly quadruples the risk of brain swelling or hemorrhage compared to non-carriers; heterozygotes are at increased risk as well, but to a lesser extent.
- immunologic disease requiring immunoglobulins, monoclonal antibodies, immunosuppressants, or plasmapheresis
- coagulopathy (e.g., platelets <50,000 or INR > 1.5)

References: (1) van Dyck CH, et al. Lecanemab in early Alzheimer's Disease. *N Engl J Med.* 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](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.