Lecanemab-irmb (LEQEMBI)
Criteria for Use
August 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive lecanemab.

☐ Any medical, neurological, or mental health condition that may be a contributing/primary cause of cognitive impairment

☐ Age less than 65 years

☐ Contraindication to brain MRI

☐ Transient ischemic attack, stroke, or seizures within the past year

☐ Evidence of other clinically significant lesions on brain MRI that indicate another cause of dementia

☐ Evidence on screening MRI that would exclude treatment^1

☐ ApoE e4 homozygote

☐ Any immunological disease which is not controlled, or which requires treatment with biologic drugs

☐ Untreated bleeding disorder, platelet count <50,000 x 10^9/L, or international normalized ratio [INR] greater than 1.5

☐ Thyroid stimulating hormone above normal range (TSH > 5 mU/L if < 65 years old; TSH > 7.5 mU/L if > 65 years old)

☐ Low serum vitamin B12 level

☐ Untreated human immunodeficiency virus (HIV)

☐ Malignant neoplasm under active therapy

☐ Answer "yes" to Columbia-Suicide Severity Rating Scale (C-SSRS) suicidal ideation item 4 or 5, or any suicidal behavior assessment within the past 6 months ^2

☐ Hospitalized or treated for suicidal behavior in the past 5 years

☐ Current substance use disorder or positive urine drug screen

☐ Receiving medication(s) with anti-platelet or anti-coagulant properties (e.g., apixaban, clopidogrel, NSAIDs, t-PA)

Inclusion Criteria

ALL of the following must be fulfilled to meet criteria.

☐ Prescriber is a VA (not VA Community care) board certified neurologist, geriatric psychiatrist, or geriatrician who specializes in treating dementia

☐ Patient has a signed informed consent on file; if genotype testing is not performed, the patient and provider accept the risk

☐ Patient meets criteria for mild cognitive impairment (MCI) or mild Alzheimer's disease (AD) dementia

☐ Patient has had an MRI scan within the last 3 months

☐ Amyloid PET imaging and/or cerebrospinal fluid (CSF) analysis consistent with Alzheimer's disease (e.g., Beta-amyloid (1-42) (Abeta42) < 1026 pg/ml

☐ Functional Assessment Staging Test (FAST) Stage score of 2-4, meeting criteria for MCI or mild AD dementia

☐ Mini-Mental State Examination (MMSE) score > 21, or Saint Louis University Mental Status (SLUMS) score or Montreal Cognitive Assessment (MoCA) score of > 16

☐ Neuroradiology is available to review serial MRI scans, either at site, or through National Teleradiology

☐ A process is in place before starting therapy to ensure the provider and pharmacy are notified to hold the infusion until the ordering physician can assess the patient and decide whether to continue treatment

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Prepared: February 2023. Updated July 2023, August 2023. Contact: Matthew A. Fuller, Pharm.D., National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 12PBM

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1. Screening MRI that shows evidence of: more than 4 microhemorrhages; a single macro hemorrhage greater than 10 mm at greatest diameter; an area of superficial siderosis; evidence of vasogenic edema; evidence of acute/subacute cerebral contusion, acute/subacute stroke, aneurysms, vascular malformations, or infective lesions; severe small vessel, or white matter disease; space occupying lesions; or intra-axial brain tumors
2. cssrs-screen-version-instrument.pdf (cms.gov)