Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 15, 2023

Leqembi™ (lecanemab-irmb)

LENGTH OF AUTHORIZATION: Six months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**

- Patient has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia as evidenced by *all* of the following:
  - Clinical Dementia Rating (CDR)-Global score of 0.5 to 1
  - Memory Box score ≥ 0.5
  - Mini-Mental State Examination (MMSE) score 22 to 30
  - Objective evidence of cognitive impairment at screening
  - Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) assessment of amyloid beta (1-42) is positive for amyloid beta plaque; **AND**

- Prescriber attests that conditions causing similar symptoms have been ruled out (e.g., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, normal pressure hydrocephalus); **AND**

- Prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**

- Patient does not have risk factors for intracerebral hemorrhage (e.g., prior cerebral hemorrhage > 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel or white matter disease); **AND**

- Patient has not had a stroke, transient ischemia attack (TIA), or seizure in the last 12 months; **AND**

- Patient has not demonstrated clinically significant and unstable psychiatric illness in the last 6 months; **AND**

- Patient does not have a history of alcohol or substance abuse within the last 12 months; **AND**

- Patient is not currently receiving anti-platelet agents (with the exception of prophylactic aspirin or clopidogrel), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin); **AND**

- Brain magnetic resonance imaging (MRI) has been obtained within 12 months prior to treatment initiation; **AND**

- Baseline disease severity has been assessed using an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-

Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]).

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Scoring on an objective measure/tool (e.g., ADAS-Cog 13; ADCS-ADL-MCI; MMSE; CDR-SB) demonstrates improvement, stability, or slowing in cognitive and/or functional impairment; **AND**
- Patient has not progressed to moderate or severe AD; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., severe hypersensitivity reactions); **AND**
- Patient has undergone MRI prior to the 5th, 7th, and 14th infusions to monitor for ARIA with edema (ARIA-E) or ARIA with hemosiderin deposition (ARIA-H).

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 500 mg/5 mL (100 mg/mL) and 200 mg/2 mL (100 mg/mL) single-dose vials.