Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 9, 2021 August 4, 2021, October 2, 2023

ADUHELM® (aducanumab-avwa)

LENGTH OF AUTHORIZATION: 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient has mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe AD) as evidenced by all the following:
  - Clinical Dementia Rating (CDR)-Global Score of 0.5; **AND**
  - Objective evidence of cognitive impairment at screening; **AND**
  - Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive); **AND**
  - Positron Emission Tomography (PET) scan is positive for amyloid beta plaque; **AND**
- Other conditions mimicking, but of non-Alzheimer's dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus); **AND**
- Drug must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
- Patient has received a baseline brain magnetic resonance imaging (MRI) and confirmed the presence of amyloid beta pathology prior to initiating treatment (within 1 year prior); **AND**
- Patient does not have any of the following within 1 year of treatment initiation: pre-treatment localized superficial siderosis, ≥ 10 brain microhemorrhages, or brain hemorrhage > 1 cm; **AND**
- Prescriber has assessed and documented baseline disease severity utilizing 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 continues to meet the above criteria; **AND**
- Patient has not had unacceptable toxicity from the drug (e.g., amyloid related imaging abnormalities [ARIA]-edema [ARIA-E], severe hypersensitivity reactions); **AND**
- Patient has responded to therapy compared to pre-treatment baseline as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in ≥ 1 of the following (not all-inclusive) objective measures assessed and documented at baseline: ADAS-Cog 13, ADCS-ADL-MCI, MMSE, or CDR-SB; **AND**
- Patient has not progressed to moderate or severe AD; **AND**
- Patient must continue maintenance therapy at the recommended dosage per product labeling; **AND**
- Patient has received MRI monitoring throughout therapy including an MRI prior to the 5th, 7th, 9th, and 12th doses for monitoring of ARIA-hemosiderin (ARIA-H) microhemorrhages; **AND**
- Prescriber has determined ARIA-E and ARIA-H severity to determine if dosing may continue or should be suspended (see product labeling).

ARIA Classification and Radiographic Severity†			
Severity	**ARIA-E (based on FLAIR hyperintensity)**	**ARIA-H microhemorrhage (quantity of new incident microhemorrhages)**	**ARIA-H superficial siderosis (quantity of superficial siderosis focal areas)**
Mild	confined to sulcus and or cortex/subcortical white matter in 1 location < 5 cm	≤ 4	1
Moderate	5 to 10 cm, or > 1 site of involvement, each measuring < 10 cm	5 to 9	2
Severe	> 10 cm, often with significant subcortical white matter and/or sulcal involvement; ≥ 1 separate sites of involvement may be noted	≥ 10	>2

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 170 mg/1.7 mL and 300 mg/3 mL solution in a single-dose vial for intravenous infusion