Prior Authorization Group Description	**Anti-amyloid Monoclonal Antibodies (mAb)**
Drugs	Aduhelm (aducanumab) Leqembi (lecanemab) *****Initial authorizations and reauthorizations must be approved by a Medical Director*****
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	None
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	**Initial Authorization** • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD • The request is for an FDA approved dose • Documentation of the following: o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan • If the request is for an anti-amyloid mAb approved by the FDA for the treatment of AD based upon evidence of efficacy from a change in a surrogate endpoint (e.g. amyloid reduction), the member is currently enrolled in a randomized controlled trial conducted under an investigational new drug (IND) application. **Reauthorization** • The request is for an FDA approved dose • Patient continues to have diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD

Revision/Review Date: 4/2023	• Patient continues to be enrolled in a randomized controlled trial conducted under an investigational new drug (IND) application.
	• Before the 7th and 13th doses, documentation (i.e. chart notes, test results) of repeat MRI scan to monitor for amyloid related imaging abnormalities (ARIA) including the following:
	  o Type of ARIA (-edema [E] or hemosiderin deposition [H]), if any
	  o Severity of ARIA (mild, moderate, severe), if any
	  o If severe ARIA-H, approval of continued therapy is contingent upon repeat MRI demonstrating radiographic stabilization
	• CDR-G score of 0.5 (very mild dementia)
	• RBANS DMI score ≤ 85 (low average)
	• MMSE score of 24-30
	• Patient is not taking any medications that can substantially contribute to cognitive impairment (i.e. strong anticholinergics such as first-generation antihistamines, tricyclic antidepressants; benzodiazepines; antipsychotics; barbiturates; skeletal muscle relaxants; see Beer's List)
	• Not currently using blood thinners (except aspirin)
	• No recent (past 1 year) history of stroke or TIA
	• Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.