

Prior Authorization Group Description	<u>Anti-amyloid Monoclonal Antibodies</u>
Drugs	<u>Aduhelm (aducanumab)</u>
Covered Uses	<u>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.</u>
Exclusion Criteria	<u>Patients with moderate to severe Alzheimer’s Disease (AD)</u> <u>Patients with neurodegenerative disease caused by other than AD</u>
Required Medical Information	<u>See “Other Criteria”</u>
Age Restrictions	<u>None</u>
Prescriber Restrictions	<u>Prescriber must be a neurologist</u>
Coverage Duration	<u>For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months</u> <u>For reauthorization: if all of the conditions are met, the request will be approved for 6 months.</u>
Other Criteria	<p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> • <u>Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD</u> • <u>The request is for an FDA approved dose</u> • <u>Documentation of BOTH of the following:</u> <ul style="list-style-type: none"> ○ <u>Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan</u> ○ <u>Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan</u> • <u>Clinical Dementia Rating Global (CDR-G) score of 0.5 (very mild dementia)</u> • <u>Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index (DMI) score ≤ 85 (low average)</u> • <u>Mini-Mental State Examination (MMSE) score ≥ 24 (questionably significant impairment)</u> • <u>Patient is not taking any chronic 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)</u> • <u>Not currently using blood thinners (except aspirin)</u>

- No recent (past 1 year) history of stroke or transient ischemic attack (TIA)

Reauthorization

- The request is for an FDA approved dose
- 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:
 - Type of ARIA (-edema [E] or hemosiderin deposition [H]), if any
 - Severity of ARIA (mild, moderate, severe), if any
 - 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 \leq 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

Revision/Review
Date: 7/2021

If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.