

lt's Wholecare.

Updated: 06/2021 PARP Approved: 07/2021

Prior Authorization Criteria **Aduhelm (aducanumab-avwa)**

All requests for Aduhelm (aducanumab-avwa) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of **Alzheimer's disease** and the following criteria is met:

- Must be prescribed by or in consultation with a neurologist
- Must have mild cognitive impairment (MCI) or mild dementia consistent with Stage 3 or 4 Alzheimer's disease confirmed by meeting ALL of the following within the past 6 months:
 - o Mini-Mental State Examination (MMSE) score of 24-30
 - o Clinical Dementia Rating global score (CDR-GS) of 0.5
 - o Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score ≤ 85
- Must provide documentation of a brain MRI within the past year
- Must provide documentation of a PET scan confirming presence of amyloid pathology
- Must provide chart documentation showing that all medical or neurological conditions (other than Alzheimer's) that might be a contributing cause of the member's cognitive impairment have been ruled out.
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to ONE of the following:
 - o Cholinesterase inhibitor (e.g. donepezil)
 - Memantine
- Must not have any of the following:
 - o Stroke, TIA, or unexplained loss of consciousness in the past year
 - o Clinically significant unstable psychiatric illness in past 6 months
 - History of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within the past year
 - o Impaired renal or liver function
 - o HIV infection
 - Significant systematic illness or infection in the past 30 days
 - o Relevant brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities
 - Contraindications to MRI or PET scans
 - o Alcohol or substance abuse in the past year
 - Taking blood thinners (except for aspirin at a prophylactic dose or less)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- Reauthorization criteria:
 - Must have mild cognitive impairment (MCI) or mild dementia consistent with Stage 3 or 4 Alzheimer's disease confirmed by ONE of the following within the past 6 months:

 \overrightarrow{CDR} -GS of 0.5 or 1.0

- MMSE score ≥ 18
- o Must not have any of the following:
 - Stroke, TIA, or unexplained loss of consciousness in the past year
 - History of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within the past vear

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- Impaired renal or liver function
- HIV infection
- Relevant brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities
- Contraindications to MRI or PET scans
- Alcohol or substance abuse in the past year
- Taking blood thinners (except for aspirin at a prophylactic dose or less)
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



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ADUHELM (ADUCANUMAB-AVWA) PRIOR AUTHORIZATION FORM

					t results, or chart documentation	
as applicable to Gateway Health SM Pharmacy Services. FAX: (888) 245-2049						
If needed, you may call to speak to a Pharmacy Services Representative. PHONE : (800) 392-1147 Monday through Friday 8:30am to 5:00pm						
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ADUHELM (ADUCANUMAB-AVWA) PRIOR AUTHORIZATION FORM (CONTINUED)- PAGE 2 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway HealthSM Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm MEMBER INFORMATION Member Name: DOB: Gateway ID: Member weight: Height: REAUTHORIZATION What is the disease severity?
Mild Cognitive Impairment (MCI)
Mild dementia
Moderate dementia
Severe dementia Please provide the most recent date administered and score of the following tests: Mini-Mental State Examination (MMSE) Score, Date: ___ Clinical Dementia Rating global score (CDR-GS), Date: Score: Please indicate if any of the following apply to the member (check all that apply): Stroke, TIA, or unexplained loss of consciousness in the past year History of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within the past year Impaired renal or liver function HIV infection Relevant brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities Contraindications to MRI or PET scans Alcohol or substance abuse in the past year Taking blood thinners (except for aspirin at a prophylactic dose or less) SUPPORTING INFORMATION or CLINICAL RATIONALE Prescribing Provider Signature Date