Gateway Health℠ It'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:
    - Mini-Mental State Examination (MMSE) score of 24-30
    - Clinical Dementia Rating global score (CDR-GS) of 0.5
    - 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:
    - Cholinesterase inhibitor (e.g. donepezil)
    - Memantine
- Must not have any of the following:
    - Stroke, TIA, or unexplained loss of consciousness in the past year
    - 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
    - Impaired renal or liver function
    - HIV infection
    - Significant systematic illness or infection in the past 30 days
    - 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)
- 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:

        - CDR-GS of 0.5 or 1.0
        - MMSE score ≥ 18
    - 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 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)
- **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

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ 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

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

What is the disease severity? ☐ Mild Cognitive Impairment (MCI) ☐ Mild dementia ☐ Moderate dementia ☐ Severe dementia

Please provide the date administered and score of the following tests:
Mini-Mental State Examination (MMSE) Score, Date: _____ Score: _____
Clinical Dementia Rating global score (CDR-GS), Date: _____ Score: _____
Repeatable Battery for Assessment of Neuropsychological Status (RBANS), Date: _____ Score: _____

Has the member had an MRI within the past year? ☐ Yes ☐ No
Has the member had a PET scan confirming amyloid pathology? ☐ Yes ☐ No

Have all medical or neurological conditions other than Alzheimer's been ruled out? *Chart documentation is required*. ☐ Yes ☐ No

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
- ☐ 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
- ☐ Impaired renal or liver function
- ☐ HIV infection
- ☐ Significant systematic illness or infection in the past 30 days
- ☐ 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)

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

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ADUHELM (ADUCANUMAB-AVWA)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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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: _____ Score: _____
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