HIGHMARK HEALTH OPTIONS

Updated: 01/2023
DMMA Approved: 02/2023

Request for Prior Authorization for Alzheimer's Antiamyloid Monoclonal Antibodies
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Alzheimer's Antiamyloid Monoclonal Antibodies require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Alzheimer's Antiamyloid Monoclonal Antibodies includes Aduhelm (aducanumab) and Leqembi (lecanemab). New products with this classification will require the same documentation.

Prior Authorization Criteria:

Coverage may be provided with a diagnosis of **Alzheimer's disease** (AD) 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 BOTH of the following within the past 6 months:
  - Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1.0
  - Mini-Mental State Examination (MMSE) score of 22-30
- Must provide documentation of a brain MRI within the past year
- Must provide documentation of a PET scan or cerebrospinal fluid (CSF) testing confirming presence of beta-amyloid plaques
- 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 a cholinesterase inhibitor (ie. donepezil)
- For Aduhelm (aducanumab), 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)
- For Leqembi (lecanemab), must not have any of the following:
  - History of TIA, stroke, or seizures in the past year
  - Geriatric Depression Scale (GDS) score ≥ 8
  - Contraindications to MRI scanning

  - Clinically significant lesions on brain MRI scan that could indicate a diagnosis other than Alzheimer's disease
  - Other significant pathological findings on brain MRI, including but not limited to: more than 4 microhemorrhages; a single macrohemorrhage > 10 mm; an area of superficial siderosis; evidence of vasogenic edema; evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions; evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; space occupying lesions; or brain tumors
  - Bleeding disorder that is not under adequate control
  - Prolonged QT/QTc interval
- 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
  - For Aduhelm (aducanumab), 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)
  - For Leqembi (lecanemab), must not have any of the following:
    - History of TIA, stroke, or seizures in the past year
    - Geriatric Depression Scale (GDS) score ≥ 8
    - Contraindications to MRI scanning
    - Clinically significant lesions on brain MRI scan that could indicate a diagnosis other than AD
    - Other significant pathological findings on brain MRI, including but not limited to: more than 4 microhemorrhages; a single macrohemorrhage > 10 mm; an area of superficial siderosis; evidence of vasogenic edema; evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions; evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; space occupying lesions; or brain tumors
    - Bleeding disorder that is not under adequate control
    - Prolonged QT/QTc interval
- **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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

HIGHMARK HEALTH OPTIONS

Updated: 01/2023
DMMA Approved: 02/2023

ALZHEIMER'S DISEASE ANTIAMYLOID MONOCLONAL ANTIBODIES
PRIOR AUTHORIZATION FORM – PAGE 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

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

REQUESTED DRUG INFORMATION

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

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

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: _____

Has the member had an MRI within the past year? ☐ Yes ☐ No
Has the member had a PET scan or CSF testing confirming presence of beta-amyloid plaques? ☐ Yes ☐ No

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

For Aduhelm, 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)

***** Continued on next page *****

HIGHMARK HEALTH OPTIONS

Updated: 01/2023
DMMA Approved: 02/2023

ALZHEIMER'S DISEASE ANTIAMYLOID MONOCLONAL ANTIBODIES 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 Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

MEMBER INFORMATION

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

MEDICAL HISTORY (Complete for ALL requests) - continued

For Leqembi, please indicate if any of the following apply to the member (check all that apply):

- ☐ History of TIA, stroke, or seizures in the past year
- ☐ Geriatric Depression Scale (GDS) score ≥ 8
- ☐ Contraindications to MRI scanning
- ☐ Clinically significant lesions on brain MRI scan that could indicate a diagnosis other than AD
- ☐ Other significant pathological findings on brain MRI, including but not limited to: more than 4 microhemorrhages; a single macrohemorrhage > 10 mm; an area of superficial siderosis; evidence of vasogenic edema; evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions; evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; space occupying lesions; or brain tumors
- ☐ Bleeding disorder that is not under adequate control
- ☐ Prolonged QT/QTc interval

CURRENT or PREVIOUS THERAPY

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

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: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date