HIGHMARK WHOLECARE

Updated: 08/2024
PARP Approved: 09/2024

Prior Authorization Criteria

Alzheimer's Antiamyloid Monoclonal Antibodies

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 Leqembi (lecanemab) and Kisunla (donanemab). New products with this classification will require the same documentation.

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 ONE of the following within the past 6 months:
    - Mini-Mental State Examination (MMSE) score of 20-30
    - Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1.0
- Must have objective evidence of cognitive impairment
- 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 have discussed how testing for ApoE ε4 status informs the risk of developing ARIA and offered testing for ApoE ε4 status
- 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 (e.g. donepezil)
- Must not have any of the following:
    - History of TIA, stroke, or seizures in the past year
    - Contraindications to MRI scanning
    - Bleeding disorder that is not under adequate control
    - Clinically significant lesions on brain MRI scan that could indicate a diagnosis other than Alzheimer's disease
    - Significant pathological findings on brain MRI
- 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 stabilization or improvement in cognitive scores from baseline
    - 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
- **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.

HIGHMARK WHOLECARE

Updated: 08/2024
PARP Approved: 09/2024

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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 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:	
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:	

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

Is there objective evidence of cognitive impairment? ☐ Yes ☐ No

Has testing for ApoE 4 status been discussed and how this affects the risk of developing ARIA? ☐ Yes ☐ No
Has ApoE 4 status testing been offered? ☐ 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):
- ☐ History of TIA, stroke, or seizures in the past year
- ☐ 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
- ☐ Bleeding disorder that is not under adequate control

CURRENT or PREVIOUS THERAPY

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

HIGHMARK WHOLECARE

Updated: 08/2024
PARP Approved: 09/2024

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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

MEMBER INFORMATION

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

REAUTHORIZATION

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

What is the outcome of therapy since baseline?
- ☐ Improvement in cognitive scores
- ☐ Stabilization of cognitive scores
- ☐ Decline of cognitive scores

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