Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 30, 2026	July 6, 2026	*See below

SUBJECT

Prior Authorization of Amyloid-Targeted Monoclonal Antibodies (MABs) – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.pa.gov/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Amyloid-Targeted Monoclonal Antibodies (MABs) submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Amyloid-Targeted MABs to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

*01-26-59	09-26-59	27-26-45	33-26-48
02-26-45	11-26-44	30-26-44	
03-26-45	14-26-48	31-26-60	
08-26-59	24-26-58	32-26-44	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/agencies/dhs/departments-offices/omap-info

DISCUSSION:

During the May 12, 2026, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Amyloid-Targeted MABs:

- Deletion of the guidelines related to Aduhelm (aducanumab).
- Deletion of the guidelines related to Leqembi (lecanemab-irmb).
- Addition of guidelines to determine medical necessity that apply to all drugs in this class, which currently includes Leqembi (lecanemab-irmb) and Kisunla (donanemab-azbt).

The revisions to the guidelines to determine medical necessity of prescriptions for Amyloid-Targeted MABs submitted for prior authorization, as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Amyloid-Targeted MABs are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Amyloid-Targeted MABs) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.pa.gov/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/agencies/dhs/resources/pharmacy-services/clinical-guidelines

I. Requirements for Prior Authorization of Amyloid-Targeted Monoclonal Antibodies (MABs)

A. Prescriptions That Require Prior Authorization

All prescriptions for Amyloid-Targeted MABs must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Amyloid-Targeted MAB, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Amyloid-Targeted MAB for an indication that is consistent with the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**

2. Has at least **two** of the following:

   a. Mini-Mental State Examination (MMSE) score of greater than or equal to 18 and less than or equal to 23,
   b. Montreal Cognitive Assessment (MoCA) score of greater than or equal to 18 and less than or equal to 25,
   c. Global Clinical Dementia Rating Scale (CDR) score of 0.5 or 1;

   AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling; **AND**

4. Is prescribed the Amyloid-Targeted MAB by a dementia specialist (e.g., neurologist, psychiatrist, or geriatrician) and the documentation reflects that the beneficiary will be monitored at least once every three months; **AND**

5. Has baseline magnetic resonance imaging (MRI) results as recommended in the FDA-approved package labeling; **AND**

6. Has **one** of the following confirming beta-amyloid pathology:

   a. Positive amyloid positron emission tomography scan,
   b. Positive cerebrospinal fluid biomarker testing (Aβ42/40 ratio or total tau/Aβ42 ratio),
   c. A positive FDA-cleared plasma biomarker assay validated for the identification of brain amyloid pathology (e.g., p-tau217 ratio-based assays);

   AND

7. Does not have **any** of the following:

a. A contraindication to MRI scanning (e.g., cardiac pacemaker/defibrillator or ferromagnetic metal implants),
b. A medical or neurological condition (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment,
c. A history of stroke, transient ischemic attack (TIA), or seizures in the past year,
d. A bleeding disorder that is not under adequate control,
e. Any significant pathological findings on brain MRI at screening that indicate an increased risk for amyloid-related imaging abnormalities or intracerebral hemorrhage.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AMYLOID-TARGETED MABs: The determination of medical necessity of a request for renewal of a prior authorization for an Amyloid-Targeted MAB that was previously approved will take into account whether the beneficiary:

1. Continues to experience medical benefit from and tolerability of the Amyloid-Targeted MAB based on the prescriber's assessment; **AND**

2. Has repeat testing and documented results of at least **two** of the following:

   a. MMSE,
   b. MoCA,
   c. CDR;

   AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling; **AND**

4. **All** of the following:

   a. Is prescribed the Amyloid-Targeted MAB by a dementia specialist (e.g., neurologist, psychiatrist, or geriatrician),
   b. The documentation reflects that the beneficiary was monitored and assessed by the prescribing dementia specialist at least every three months,
   c. The documentation reflects that the beneficiary will continue to be monitored and assessed by the prescribing dementia specialist at least every three months;

   AND

5. Does not have **any** of the following:

a. A contraindication to MRI scanning (e.g., cardiac pacemaker/defibrillator or ferromagnetic metal implants),
b. A medical or neurological condition (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment,
c. A history of stroke, TIA, or seizures in the past year,
d. A bleeding disorder that is not under adequate control;

AND

6. Is continuing treatment with the Amyloid-Targeted MAB based on recent MRI results as recommended in the FDA-approved package labeling.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Amyloid-Targeted MAB. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Phase 3 NCT03887455: A Study to Confirm Safety and Efficacy of Lecanemab in Participants With Early Alzheimer's Disease.
2. Kisunla [package insert]. Indianapolis, IN: Eli Lilly and Company.; July 2025.
3. Schindler SE, Galasko D, et al. Acceptable performance of blood biomarker tests of amyloid pathology - recommendations from the Global CEO Initiative on Alzheimer's Disease. Nat Rev Neurol. 2024 Jul;20(7):426-439.
4. Hansson O, Edelmayer RM, et al. The Alzheimer's Association appropriate use recommendations for blood biomarkers in Alzheimer's disease. Alzheimers Dement. 2022 Dec;18(12):2669-2686.