pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 28, 2023	July 10, 2023	*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.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

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

*01-23-09	09-23-09	27-23-03	33-23-09
02-23-02	11-23-02	30-23-06	
03-23-02	14-23-02	31-23-10	
08-23-13	24-23-08	32-23-02	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the April 26, 2023, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Amyloid-Targeted MABs:

- Revision of the prior authorization guideline name from Aduhelm (aducanumab) to Amyloid-Targeted Monoclonal Antibodies (MABs).
- Revision to clarify that the prior authorization guidelines are applicable to all Amyloid-Targeted MABs.
- Revision to include cerebrospinal fluid biomarker testing as an option to detect beta-amyloid plaques.
- Addition of prior authorization guidelines for all requests for an Amyloid-Targeted MAB that the beneficiary does not have a contraindication to magnetic resonance imaging scanning or a medical or neurological condition (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment.
- Addition of initial and renewal prior authorization guidelines specific to Leqembi (lecanemab-irmb).

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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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 included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**

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

3. 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 3 months; **AND**

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

5. Has a positron emission tomography scan or cerebrospinal fluid biomarker testing positive for beta-amyloid plaques; **AND**

6. Does not have **either** 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;

   AND

7. For Aduhelm (aducanumab), **both** of the following:

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

      i. Mini-Mental State Examination (MMSE) score of at least 24,
      ii. Montreal Cognitive Assessment (MoCA) score of at least 18,
      iii. Global Clinical Dementia Rating Scale (CDR) score of 0.5

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

i. A history of stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year,
ii. Poorly controlled diabetes mellitus,
iii. A brain MRI showing evidence of acute or sub-acute micro- or macro-hemorrhage, greater than 4 microhemorrhages, cortical infarct, or greater than 1 lacunar infarct,
iv. Current use of anticoagulants (except for aspirin at a prophylactic dose or less);

AND

8. For Leqembi (lecanemab-irmb), **both** of the following:

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

i. MMSE score of at least 22,
ii. MoCA score of at least 17,
iii. CDR score of 0.5 or 1

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

i. A history of stroke, TIA, or seizures in the past year,

ii. A bleeding disorder that is not under adequate control,

iii. Any of the following significant pathological findings on brain MRI at screening:

a) More than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter),
b) A single macrohemorrhage >10 mm at greatest diameter,
c) An area of superficial siderosis,
d) Evidence of vasogenic edema,
e) Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
f) Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
g) Space occupying lesions,
h) Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter).

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. Does not have **either** 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;

    AND

5. **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 3 months,
    c. The documentation reflects that the beneficiary will continue to be monitored and assessed by the prescribing dementia specialist at least every 3 months;

    AND

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

    a. For Aduhelm (aducanumab):

        i. A history of stroke or TIA or unexplained loss of consciousness in the past year,
        ii. Poorly controlled diabetes mellitus,

iii. A brain MRI showing evidence of acute or sub-acute micro- or macro-hemorrhage, greater than 4 microhemorrhages, cortical infarct, or greater than 1 lacunar infarct,
iv. Current use of anticoagulants (except for aspirin at a prophylactic dose or less)

b. For Leqembi (lecanemab-irmb):

i. A history of stroke, TIA, or seizures in the past year,

ii. A bleeding disorder that is not under adequate control,

iii. **Any** of the following significant pathological findings on brain MRI:

a) Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
b) Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
c) Space occupying lesions,
d) Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter);

AND

7. 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. Aduhelm [package insert]. Cambridge, MA: Biogen Inc.; July 2021.

2. Budd Haeberlein S, Aisen PS, Barkhof F, et al. Two Randomized Phase 3 Studies of Aducanumab in Early Alzheimer's Disease. J Prev Alzheimers Dis. 2022;9(2):197-210. doi:10.14283/jpad.2022.30
3. Cummings J, Aisen P, Apostolova LG, et al. Aducanumab: Appropriate use recommendations. J Prev Alzheimers Dis 8, 398–410 (2021). https://doi.org/10.14283/jpad.2021.41.
4. Leqembi [package insert]. Nutley, NJ: Eisai Inc.; January 2023.
5. Mintun MA, Lo AC, Duggan Evans C, Wessels AM, Ardayfio PA, Andersen SW, Shcherbinin S, Sparks J, Sims JR, Brys M, Apostolova LG, Salloway SP, Skovronsky DM. Donanemab in Early Alzheimer's Disease. N Engl J Med. 2021 May 6;384(18):1691-1704. doi: 10.1056/NEJMoa2100708. Epub 2021 Mar 13. PMID: 33720637.
6. Phase 3 NCT03887455: A Study to Confirm Safety and Efficacy of Lecanemab in Participants With Early Alzheimer's Disease. Available at: https://clinicaltrials.gov/ct2/show/NCT03887455
7. Salloway S, Chalkias S, Barkhof F, et al. Amyloid-Related Imaging Abnormalities in 2 Phase 3 Studies Evaluating Aducanumab in Patients With Early Alzheimer Disease. JAMA Neurol. 2022;79(1):13-21. doi:10.1001/jamaneurol.2021.4161
8. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody [published correction appears in Alzheimers Res Ther. 2022 May 21;14(1):70]. Alzheimers Res Ther. 2021;13(1):80. Published 2021 Apr 17. doi:10.1186/s13195-021-00813-8
9. Trzepacz PT, Hochstetler H, Wang S, Walker B, Saykin AJ; Alzheimer’s Disease Neuroimaging Initiative. Relationship between the Montreal Cognitive Assessment and Mini-mental State Examination for assessment of mild cognitive impairment in older adults. BMC Geriatr. 2015 Sep 7;15:107. doi: 10.1186/s12877-015-0103-3. PMID: 26346644; PMCID: PMC4562190.
10. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in Early Alzheimer's Disease. N Engl J Med. 2023;388(1):9-21. doi:10.1056/NEJMoa2212948