


<b>ISSUE DATE</b>  January 12, 2022	<b>EFFECTIVE DATE</b>  February 1, 2022	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Aduhelm (aducanumab) – Pharmacy Services		<b>BY</b>   Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

**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:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of prescriptions for Aduhelm (aducanumab).
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Aduhelm (aducanumab) 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 Aduhelm (aducanumab) to the appropriate managed care organization.

**BACKGROUND:**

*01-22-03	09-22-02	27-22-01	33-22-02
02-22-01	11-22-02	30-22-01	
03-22-01	14-22-01	31-22-03	
08-22-03	24-22-01	32-22-01	

**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 website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department's 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.

**DISCUSSION:**

During the November 3, 2021, meeting, the DUR Board recommended that the Department require prior authorization of prescriptions for Aduhelm (aducanumab) to ensure appropriate utilization of Aduhelm (aducanumab). The DUR Board recommended guidelines to determine medical necessity of prescriptions for Aduhelm (aducanumab) that 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 Aduhelm (aducanumab) 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 Aduhelm (aducanumab)) 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>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Aduhelm (aducanumab)**

**A. Prescriptions That Require Prior Authorization**

All prescriptions for Aduhelm (aducanumab) must be prior authorized.

**B. Review of Documentation for Medical Necessity**

In evaluating a request for prior authorization of a prescription for Aduhelm (aducanumab), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Aduhelm (aducanumab) 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 Aduhelm (aducanumab) by a dementia specialist (e.g., neurologist, psychiatrist, or geriatrician) who will monitor and assess the beneficiary 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 (PET) scan positive for beta-amyloid plaques; **AND**
6. Has at least **two** of the following:
  - a. Mini-Mental State Examination (MMSE) score of at least 24,
  - b. Montreal Cognitive Assessment (MoCA) score of at least 18,
  - c. Global Clinical Dementia Rating Scale (CDR) score of 0.5;

**AND**

7. Does not have **any** of the following:
  - a. A medical or neurological condition (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment,
  - b. A history of stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year,
  - c. Poorly controlled diabetes mellitus,
  - d. 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,
  - e. Current use of anticoagulants (except for aspirin at a prophylactic dose or less).

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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 ADUHELM (ADUCANUMAB): The determination of medical necessity of a request for renewal of a prior authorization for Aduhelm (aducanumab) that was previously approved will take into account whether the beneficiary:

1. Continues to experience medical benefit from and tolerability of Aduhelm (aducanumab) 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 Aduhelm (aducanumab) by a dementia specialist (e.g., neurologist, psychiatrist, or geriatrician),
  - b. Was monitored and assessed by the prescribing dementia specialist at least every 3 months,
  - c. Will continue to be monitored and assessed by the prescribing dementia specialist at least every 3 months;

**AND**

5. Does not have **any** of the following:
  - a. A medical or neurological condition (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment,
  - b. A history of stroke or TIA or unexplained loss of consciousness in the past year,
  - c. Poorly controlled diabetes mellitus,
  - d. 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,
  - e. Current use of anticoagulants (except for aspirin at a prophylactic dose or less);

**AND**

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6. Is continuing treatment with Aduhelm (aducanumab) 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 Aduhelm (aducanumab). 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. Cummings J, Aisen P, Apostolova LG, et al. Aducanumab: Appropriate use recommendations. *Alzheimers Dement* 2021.
2. Aduhelm [package insert]. Cambridge, MA; Biogen Inc. July 2021.