pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 2, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of Antihyperuricemics – 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 Antihyperuricemics submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Antihyperuricemics will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Antihyperuricemics to the appropriate MCO.

BACKGROUND:

*01-21-18	09-21-17	27-21-08	33-21-17
02-21-05	11-21-07	30-21-12	
03-21-05	14-21-08	31-21-20	
08-21-19	24-21-15	32-21-05	

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 of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 14, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Antihyperuricemics:

- Removal of the requirement for prior authorization and associated medical necessity guidelines for single-ingredient colchicine agents;
- Revision of the guideline for a non-preferred Antihyperuricemic to reflect treatment recommendations from the American College of Rheumatology; and
- Revision of the guidelines for Krystexxa (pegloticase) to reflect treatment recommendations from the American College of Rheumatology.

The revisions to the guidelines to determine medical necessity of prescriptions for Antihyperuricemics submitted for prior authorization, as recommended by the P&T Committee, 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 Antihyperuricemics 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 Antihyperuricemics) 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 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 Antihyperuricemics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihyperuricemics that meet any of the following conditions must be prior authorized:

1. A non-preferred Antihyperuricemic. See the Preferred Drug List (PDL) for the list of preferred Antihyperuricemics at: https://papdl.com/preferred-drug-list.

2. An Antihyperuricemic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

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

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. For a non-preferred Antihyperuricemic, **one** of the following:

    a. For a non-preferred xanthine oxidase inhibitor, has a documented history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of the preferred xanthine oxidase inhibitors,
    b. For a non-preferred single-ingredient colchicine agent, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred single-ingredient colchicine agents that would not be expected to occur with the requested medication,
    c. For all other non-preferred Antihyperuricemics, has a documented history of therapeutic failure of or a contraindication or intolerance to maximum tolerated doses of the preferred Antihyperuricemics that are FDA-approved or medically accepted for the beneficiary's diagnosis;

AND

6. For Krystexxa (pegloticase), **all** of the following:

   a. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist),

   b. **Both** of the following:

      i. Has a recent uric acid level that is above goal based on American College of Rheumatology guidelines

      ii. **One** of the following:

         a) Continues to have frequent gout flares (≥2 flares/year)
         b) Has non-resolving subcutaneous tophi,

   c. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents,

   d. Has documentation of counseling regarding **both** of the following:

      i. Appropriate dietary and lifestyle modifications
      ii. Discontinuation of other medications known to precipitate gout attacks (e.g., thiazide diuretics);

AND

9. If a prescription for an Antihyperuricemic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement 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 KRYSTEXXA (PEGLOTICASE): The determination of medical necessity of a request for renewal of a prior authorization for Krystexxa (pegloticase) that was previously approved will take into account whether the beneficiary:

1. Has documentation of improvement in disease severity since initiating treatment with Krystexxa (pegloticase); **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist); **AND**

4. Does not have a history of a contraindication to Krystexxa (pegloticase); **AND**

5. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents; **AND**

6. If a prescription for Krystexxa (pegloticase) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement 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.

B. 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 Antihyperuricemic. 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.

C. References

1. Mitigare [package insert]. Eatontown, NJ: West-Ward Pharmaceutical Corp.; September 2015.
2. Colcrys [package insert]. Philadelphia, PA: Mutual Pharmaceutical Company, Inc.; September 2009.
3. Krystexxa [package insert]. Lake Forest, IL; Horizon Pharma USA, Inc.; July 2018.
4. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. Arthritis Care Res (Hoboken). 2020;72(6):744-760.
5. Perez-Ruiz F. Pharmacologic urate-lowering therapy and treatment of tophi in patients with gout. In: UpToDate [internet database]. Dalbeth N, Romain PL, eds. Waltham, MA: UpToDate Inc. Updated December 16, 2020. Accessed June 28, 2021.