

ISSUE DATE September 3, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Antihyperuricemics – Pharmacy Services	BY  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: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 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 Antihyperuricemics to the appropriate managed care organization.

BACKGROUND:

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

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|-----------|----------|----------|----------|
| *01-19-50 | 09-19-46 | 27-19-44 | |
| 02-19-44 | 11-19-43 | 30-19-42 | |
| 03-19-43 | 14-19-42 | 31-19-49 | |
| 08-19-52 | 24-19-44 | 32-19-42 | 33-19-46 |

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 <http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

- 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 June 21, 2019, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Antihyperuricemics:

- Removal of the prior authorization guidelines for lesinurad-containing agents as all lesinurad-containing agents have been removed from the market and
- Addition of new prior authorization guidelines for Krystexxa (pegloticase) to ensure appropriate patient selection and drug utilization of Krystexxa (pegloticase).

The revisions to the guidelines to determine medical necessity of Antihyperuricemics, 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

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II

Pharmacy Prior Authorization Guidelines

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. A single-ingredient oral colchicine agent.
3. 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: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

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 history of a contraindication to the prescribed medication; **AND**
5. For a non-preferred Antihyperuricemic, has a documented history of therapeutic failure, intolerance, or contraindication to maximum tolerated doses of the preferred Antihyperuricemics approved or medically accepted for the beneficiary's diagnosis; **AND**
6. For a single-ingredient oral colchicine agent for the treatment of an acute gout attack, has a documented history of therapeutic failure, intolerance, or contraindication to **one** of the following at doses and frequencies consistent with medically accepted standards for the treatment of gout:
 - a. NSAIDs or COX-2 inhibitors,
 - b. Intra-articular or systemic corticosteroids;

AND

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7. For a single-ingredient oral colchicine agent for the treatment of chronic gout, **both** of the following:
- a. Has a recent uric acid level that is above goal based on American College of Rheumatology guidelines,
 - b. **One** of the following:
 - i. Failed to achieve a positive clinical response (e.g., reduction in flare rate, resolution of tophi, decrease in pain, and decreased functional impairment) using the maximum tolerated doses of standard uric acid lowering medication for the prophylaxis of gout attacks (such as xanthine oxidase inhibitors or probenecid),
 - ii. Is being prescribed colchicine in combination with a uric acid lowering medication recently started for the prophylaxis of gout attacks (such as allopurinol, probenecid, or febuxostat);

AND

9. 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. Has a recent uric acid level that is above goal based on American College of Rheumatology guidelines,
 - 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 life style modifications,
 - ii. Discontinuation of other medications known to precipitate gout attacks (e.g., thiazide diuretics);

AND

10. 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.

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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.

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 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.

D. 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.

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3. Krystexxa [package insert]. Lake Forest, IL; Horizon Pharma USA, Inc.; July 2018.
4. Becker MA and 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. Updated March 19, 2019.