pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 18, 2019	January 28, 2019	*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: 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' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and recommends preferred or non-preferred status for new drugs in therapeutic classes already included on the Preferred Drug List (PDL), changes in the status of drugs on the PDL from

*01-19-05	09-19-05	27-19-05	33-19-05
02-19-04	11-19-04	30-19-04	
03-19-04	14-19-04	31-19-05	
08-19-07	24-19-04	32-19-04	

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 to non-preferred and non-preferred to preferred, new quantity limits, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

DISCUSSION:

During the November 27, 2018, meeting, the P&T Committee recommended adding single-ingredient colchicine agents to the list of Antihyperuricemic prescriptions that require prior authorization to allow for medical necessity review of preferred single-ingredient colchicine agents on the PDL. Additionally, the P&T Committee recommended revising the guidelines to determine medical necessity specific to Zurampic (lesinurad) to apply to all lesinurad-containing agents due to the availability of combination products containing lesinurad. The proposed changes to the medical necessity guidelines were subject to public review and comment and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Antihyperuricemics are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS 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

I. Requirements for Prior Authorization of Antihyperuricemics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihyperuricemics that meet 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 the following:

1. For a non-preferred Antihyperuricemic, whether the beneficiary has a documented history of therapeutic failure, intolerance, or contraindication of the preferred Antihyperuricemics.

   AND

2. For a single-ingredient oral colchicine agent, whether the beneficiary:

   a. Does not have a contraindication to colchicine,

      AND

   b. Is age-appropriate based on package labeling,

      AND

c. Is being treated for a condition that is U.S. Food and Drug Administration (FDA) approved or a medically accepted indication,

AND

d. If being treated for an acute gout attack, has a documented history of therapeutic failure, intolerance, or contraindication to the following at doses and frequencies consistent with medically accepted standards for the treatment of gout:

i. NSAIDS or COX-2 Inhibitors,

OR

ii. Intra-articular or systemic corticosteroids.

OR

e. If being treated for chronic gout:

i. Does not have severe renal and/or hepatic impairment **OR** the dose of colchicine has been adjusted accordingly,

AND

ii. Has a recent uric acid level,

AND

iii. 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),

OR

iv. 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).

OR

f. If being treated for familial Mediterranean fever (FMF), does not have severe renal and/or hepatic impairment OR the dose of colchicine has been adjusted accordingly.

OR

3. For a lesinurad-containing agent, whether the beneficiary:

   a. Does not have a contraindication to lesinurad,

      AND

   b. Is age-appropriate according to package labeling,

      AND

   c. Is being treated for a condition that is FDA-approved or a medically accepted indication,

      AND

   d. Failed to achieve target uric acid levels using the maximum tolerated dose of a xanthine oxidase inhibitor,

      AND

   e. Does not have a CrCl < 45 mL/minute,

      AND

   f. Does not have severe hepatic impairment (Child Turcotte Pugh Class C),

      AND

   g. If being treated for hyperuricemia associated with gout, will be taking lesinurad in addition to a xanthine oxidase inhibitor.

OR

4. If the 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.

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. Treatment of Acute Gout. UpToDate ONLINE. Updated June 17, 2010. Accessed December 3, 2010.
2. Prevention of Recurrent Gout. UpToDate ONLINE. Updated October 7, 2010. Accessed December 16, 2010.
3. Zurampic (lesinurad) package insert. Wilmington, DE: AstraZeneca; December 2015.
4. Mitigare (colchicine) package insert. Eatontown, NJ: West-Ward Pharmaceutical Corp.; September 2015.
5. Colcrys (colchicine) package insert. Philadelphia, PA: Mutual Pharmaceutical Company, Inc.; September 2009.
6. Becker MA. Prevention of recurrent gout: pharmacologic urate-lowering therapy and treatment of tophi. In: UpToDate [Internet Database]. Schumacher HR, Romain PL, eds. Waltham, MA: UpToDate. Updated January 8, 2016.
7. Duzallo (lesinurad and allopurinol) package insert. Sodertalje, Sweden: AstraZeneca; August 2017.