pennsylvania
DEPARTMENT OF HUMAN SERVICES

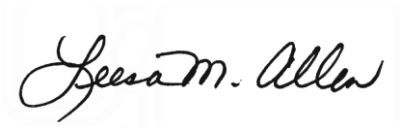
# MEDICAL ASSISTANCE BULLETIN

| ISSUE DATE | EFFECTIVE DATE | NUMBER |
|---|---|---|
| June 13, 2016 | June 13, 2016 | *See below |

**SUBJECT**

Prior Authorization of Antihyperuricemics - Pharmacy Service

**BY**



Leesa M. Allen, Deputy Secretary
Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISe to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Providers who enrolled on or before SEPTEMBER 25, 2011 must complete the revalidation process as soon as possible. DHS must complete the revalidation for all providers enrolled on or before September 25, 2011 by September 25, 2016.

## PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Antihyperuricemics for medical necessity.

## 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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

## BACKGROUND:

The Department of Human Services (Department) Drug Utilization Review (DUR) Board meets semi-annually 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 Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

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| *01-16-15 | 09-16-14 | 27-16-13 | |
| 02-16-13 | 11-16-13 | 30-16-13 | |
| 03-16-13 | 14-16-13 | 31-16-16 | |
| 08-16-14 | 24-16-14 | 32-16-12 | 33-16-13 |

**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

**DISCUSSION:**

During the March 23, 2016 meeting, the DUR Board recommended that the Department update the guidelines to determine medical necessity of Zurampic in the Antihyperuricemics class of drugs to ensure appropriate drug utilization. The Zurampic package labeling includes a black box warning regarding the increased risk of acute renal failure when Zurampic is used as monotherapy. The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The guidelines to determine the medical necessity of Zurampic are included in the attached updated provider handbook pages.

**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

SECTION II
Antihyperuricemics

## 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 prescription for a non-preferred Antihyperuricemic. See the Preferred Drug List (PDL) for the list of preferred Antihyperuricemics at: http://www.providersynergies.com/services/documents/PAM_PDL_20101115.pdf

2. A prescription for a preferred or non-preferred Antihyperuricemic with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits 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 a non-preferred Antihyperuricemic, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient has a documented history of therapeutic failure, intolerance, or contraindication of the preferred Antihyperuricemics

**OR**

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

   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 Uloric)

**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 Zurampic (lesinurad), whether the recipient:

a. Does not have a contraindication to Zurampic (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 Zurampic (lesinurad) in addition to a xanthine oxidase inhibitor

**OR**

4. The request does not meet the clinical review guideline listed above, but in the professional judgment of the physician reviewer, the therapy is medically necessary to meet the medical needs of the recipient.

5. In addition, if a prescription for either a preferred or non-preferred Antihyperuricemic is in 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/Daily Dose Limits Chapter.

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 the request for a prescription for an Antihyperuricemic. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. When a non-preferred Antihyperuricemic is approved and is determined to be therapeutically equivalent to other non-preferred Antihyperuricemics, the reviewer will take into account the cost of the drug, including the Federal Drug Rebate Program rebate and any Supplemental Rebate. The reviewer will prior authorize a prescription for the least costly therapeutically equivalent non-preferred Antihyperuricemic. If the guidelines are not met, or if the prescriber does not agree to the therapeutically equivalent non-preferred Antihyperuricemic authorized by the reviewer, 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 recipient.

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.