Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.231	**Effective Date: 01/01/2020** **Revision Date: 01/2021**
Policy Name: Antihyperuricemics	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021 annual review: no changes.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Antihyperuricemics

Reference Number: PHW.PDL.231
Effective Date: 01/01/2020
Last Review Date: 01/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Antihyperuricemics are **medically necessary** when the following criteria are met:

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.

2. A single-ingredient oral colchicine agent.

3. An Antihyperuricemic with a prescribed quantity that exceeds the quantity limit.

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

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 PA.CP.PMN.59 Quantity Limit Override.

    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 PA.CP.PMN.59 Quantity Limit Override.

    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. **Approval Duration:**

Colchicine (Colcrys, Mitigare)	Familial Mediterranean Fever (FMF)	12 months
	Gout – Treatment of Acute Attack	6 months
	Gout – Anti-Inflammatory Prophylaxis	6 months
	Pericarditis (off-label)	6 months
	Other diagnoses/indications	6 months
Lesinurad/allopurinol (Duzallo) **Lesinurad (Zurampic)**	Hyperuricemia associated with Gout	12 months
	Other diagnoses/indications	6 months
Febuxostat (Uloric)	Hyperuricemia associated with Gout	12 months
	Other diagnoses/indications	6 months
Allopurinol (Zyloprim)	All diagnoses/indications	12 months

E. 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. 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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021