Clinical Policy: Antihyperuricemics

Reference Number: PHW.PDL.231
Effective Date: 01/01/2020
Last Review Date: 11/2024

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 PA Health & 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. 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.

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 member:

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, **one** of the following:

a. For a non-preferred xanthine inhibitor, has a documented history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of the preferred xanthine oxide 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 an intolerance to the preferred Antihyperuricemics that are FDA-approved or medically accepted for the member'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:

         1. Continues to have frequent gout flares (≥2 flares/year)
         2. 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 life style modifications
      ii. Discontinuation of other medications known to precipitate gout attacks (e.g., thiazide diuretics);

   AND

7. 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 member 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 member, 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 member:

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 member 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 member, 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 member.

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. 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. Access June 28, 2021.

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
Q1 2022: policy revised according to DHS revisions effective 01/03/2022.	10/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025 annual review: no changes.	11/2024