Cigna National Formulary Coverage Policy

Effective Date..... 3/1/2023
Next Review Date..... 3/1/2024

Step Therapy
Gout Medications

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107669

Effective 2/7/23: 14302

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Uloric® (febuxostat tablets, generic)
- Zyloprim® (allopurinol tablets, generic)

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: allopurinol tablets (Zyloprim, generic)

Step 2: febuxostat tablets (Uloric, generic)

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

2. If the individual is receiving concomitant medications that have significant drug-drug interactions with the Step 1 Product, which are not noted with Uloric/febuxostat tablets (e.g., cyclosporine, chlorpropamide), approve the Step 2 Product.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Allopurinol (Zyloprim, generic), a xanthine oxidase inhibitor, is indicated for the following uses:[1]

- **Signs and symptoms of primary or secondary gout** (e.g., acute attacks, tophi, joint destruction, uric acid lithiasis, and/or nephropathy).
- **Cancer therapy which causes elevations on serum and urinary uric acid levels**, of patients with leukemia, lymphoma, and malignancies.
- **Recurrent calcium oxalate calculi**, whose daily uric acid excretion exceeds 800 mg/day for male patients and 750 mg/day for female patients.

Febuxostat (Uloric, generic), a xanthine oxidase inhibitor, is indicated for the **chronic management of hyperuricemia in patients with gout** who have had an inadequate response to a maximally titrated dose of allopurinol, or for whom treatment with allopurinol is not advisable.[2]

References

1. Zyloprim® tablets [prescribing information]. Greenville, NC: Casper; December 2018.
2. Uloric® tablets [prescribing information]. Deerfield, IL: Takeda; February 2019.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	01/18/2023