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5.70.072

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	March 22, 2019
Subject:	Uloric	**Page:**	1 of 4

Last Review Date: December 12, 2025

Uloric

Description

Uloric (febuxostat)

Background
Uloric (febuxostat) is a xanthine oxidase inhibitor that achieves its therapeutic effect by decreasing serum uric acid. Uloric is not expected to inhibit other enzymes involved in purine and pyrimidine synthesis and metabolism at therapeutic concentrations (1).

Regulatory Status
FDA-approved indication: Uloric is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable (1).

Limitations of Use:
Uloric is not recommended for the treatment of asymptomatic hyperuricemia (1).

Uloric carries a boxed warning for cardiovascular (CV) death. Gout patients with established CV disease treated with Uloric have a higher rate of CV death compared to those treated with allopurinol. The risks and benefits of Uloric should be considered when deciding to prescribe or continue patients on Uloric. Uloric should only be used in patients who have an inadequate

response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable (1).

Uloric is contraindicated in patients being treated with azathioprine or mercaptopurine (1).

A serum uric acid level of less than 6 mg/dL is the goal of antihyperuricemic therapy and has been established as appropriate for the treatment of gout (1).

The safety and effectiveness of Uloric in pediatric patients less than 18 years of age have not been established (1).

Related policies
Krystexxa

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Uloric may be considered **medically necessary** if the conditions indicated below are met.

Uloric may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Chronic gout (hyperuricemia)

AND ALL of the following:

1. Symptomatic
2. Inadequate treatment response to a maximally titrated dose of allopurinol **OR**

an intolerance or contraindication to allopurinol
3. Prescriber agrees to monitor serum uric acid levels
4. Prescriber has evaluated the patient's cardiovascular risk
5. **NOT** used concurrently with azathioprine or mercaptopurine

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Chronic gout (hyperuricemia)

AND ALL of the following:
1. Documented improvement in serum uric acid level
2. Prescriber has evaluated the patient's cardiovascular risk
3. **NOT** used concurrently with azathioprine or mercaptopurine

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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Summary
Uloric (febuxostat) is a xanthine oxidase inhibitor that achieves its therapeutic effect by decreasing serum uric acid. Uloric is not expected to inhibit other enzymes involved in purine and pyrimidine synthesis and metabolism at therapeutic concentrations. The safety and effectiveness of Uloric in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Uloric while maintaining optimal therapeutic outcomes.

References
1. Uloric [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2023.

Policy History

Date	Action
March 2019	Addition to PA
June 2019	Annual review
March 2020	Annual review
December 2021	Annual review
December 2022	Annual review. Changed policy number to 5.70.072
January 2023	Per FEP, changed approval and renewal duration to 12 months and changed uric acid level requirement on continuation to require documented improvement rather than specific serum uric acid value
March 2023	Annual review
December 2023	Annual review
December 2024	Annual review and reference update
December 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.