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**
Duzallo, Krystexxa, Zurampic

**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* in patients that are 18 years and older for the treatment of chronic symptomatic gout and if the conditions indicated below are met.

Uloric may be considered *investigational* in patients less than 18 years of age and 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. Symptomatic
2. Documented serum uric acid level <6 mg/dL
3. Prescriber has evaluated the patient’s cardiovascular risk
4. **NOT** used concurrently with azathioprine or mercaptopurine

### Policy Guidelines

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity**  
90 tablets per 90 days

**Duration**  
6 months

**Prior – Approval *Renewal* Limits**

Same as above

### Rationale

**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

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Keywords
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.