

# ULORIC (febuxostat)

### RATIONALE FOR INCLUSION IN PA PROGRAM

# **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).

#### **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



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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	[packag	e insert].	Deerfield,	IL:	Taked	a P	harmaceutical	s Amer	ica, I	nc.; <i>F</i>	\pril	2023	
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