STEP THERAPY CRITERIA

DRUG CLASS	**XANTHINE OXIDASE INHIBITORS**
BRAND NAME*	
(generic)	
	ULORIC
	(febuxostat)

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization
Ref # 540-D

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

FDA-APPROVED INDICATIONS
Uloric is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout.
Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

INITIAL STEP THERAPY
If the patient has filled a prescription for a 30 day supply of allopurinol within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of gout
  AND
- The patient has experienced an inadequate treatment response, intolerance or contraindication to allopurinol

RATIONALE
If the patient has filled a prescription for a 30 day supply of allopurinol within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient does not meet the initial step therapy criteria, then prior authorization is required.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Uloric is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. A serum uric acid level of less than 6 mg per dL is the goal of anti-hyperuricemic therapy and has been established as appropriate for the treatment of gout.[1-3] Xanthine oxidase inhibitor therapy with either allopurinol or febuxostat is recommended as the first-line pharmacologic urate-lowering therapy approach

in gout.[4] In randomized, double-blind, controlled trials comparing Uloric to allopurinol, it was demonstrated that Uloric 40 mg/day, the recommended starting dose, was as effective as up to 300 mg/day of allopurinol at lowering serum uric acid levels to goal. Coverage will be provided if the patient experienced an intolerance, inadequate treatment response, or contraindication to allopurinol and a diagnosis of gout.[1-3]

REFERENCES

1. Uloric [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; August 2017.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed December 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed December 2017.
4. Khanna D, Fitzgerald JD, Khanna PP, et al. 2012 American College of Rheumatology guidelines for management of gout. Patr 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. *Arthritis Care Res.* 2012 Oct; 64(10): 1431-1446.
5. Qaseem A, Harris RP, Forciea MA, et al. Management of Acute and Recurrent Gout: A clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2017; 166:58-68. URL: http://annals.org/aim/article/2578528/management-acute-recurrent-gout-clinical-practice-guideline-from-american-college. Accessed December 2017.

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(MS) 09/2011, 11/2011, 01/2012 (removed theophylline as contraindication to match current PI), 06/2012, 10/2012 (extended duration); (CT) 06/2013; (MS) 12/2013; (CF) 12/2014 (no grids needed), 12/2015, 06/2015 (no clinical changes); (MS) 12/2016 (removed contraindication question due to lack of denials), (SF) 12/2017
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CRITERIA FOR APPROVAL

Does the patient have a diagnosis of gout?	Yes	No
Has the patient experienced an inadequate treatment response, intolerance or contraindication to allopurinol?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	
2.	Approve, 36 months	Deny	Your plan covers this drug when you have gout and you cannot take allopurinol. Your use of this drug does not meet the requirement. This is based on the information we have.