CENTENE Corporation

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** febuxostat (Uloric®)
PAGE: 1 of 3	**REFERENCE NUMBER:** NH.PMN.57
EFFECTIVE DATE: 08/13	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 08/14, 3/17
PRODUCT TYPE: Medicaid	**REVISED:** 6/16

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Description: Uloric® is an oral, non-purine selective, 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.

Brand: Uloric® (febuxostat): 40mg tablets, 80mg tablets

FDA Labeled Indications: Chronic management of hyperuricemia in patients with gout.

Criteria for Approval:

Chronic Management of hyperuricemia in patients with gout

A. Age ≥ 18 years of age
B. Failure to achieve serum urate level of 6mg/dL or below with adherent use of allopurinol AND probenecid **OR** probenecid/colchicine at maximum tolerated doses, unless contraindicated (including drug intolerance).
C. Request does not exceed 1 tablet per day.

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Approval: Initial Approval: 12 months. Quantity Limit: 1 tablet per day. Continued Approval: 12 months if request does not exceed 1 tablet per day.

Special Instructions
➢ Treatment: 40mg once daily may increase to 80 mg once daily in patients who do not achieve serum uric acid level < 6mg/dL after 2 weeks.
➢ Administer concurrently with an NSAID or colchicine (Colcrys®) up to 6 months to prevent gout flare upon initiation of therapy.
➢ DO NOT use to treat asymptomatic or secondary hyperuricemia.
➢ DO NOT use concurrently with azathioprine (Imuran®, Azasan®) or mercaptopurine (Purinethol®).
➢ Caution in patient with history of stroke, myocardial infarction, preexisting cardiac disease or other cardiac risk factors.
➢ Caution in patients with severe hepatic disease (Child-Pugh Class C) and in patients with elevated transaminase concentration. Transaminase elevations have been observed in Uloric-treated patients.
➢ Caution in patients with severe renal impairment (CrCl <30ml/min).
➢ Pregnancy Category C

References:

1. Uloric® prescribing information. Accessed February 2016. Available at: www.uloric.com.
2. Uloric® monograph. Clinical Pharmacology. Accessed February 2016.
3. Becker MA. Prevention of recurrent gout: Pharmacologic urate-lowering therapy and treatment of tophi. Schumacher HR. (Ed), UpToDate. Waltham MA. Accessed February 2016.
4. Khanna D. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. Arthritis Care Res (Hoboken). 2012 Oct; 64(10):1431-46.

Revision Log	
Revision	**Date**
References updated.	08/14

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Changed initial approval time frame from 3 months to 12 months	06/15
Removed requirement of submission of recent baseline liver function tests as this is not a contraindication per package insert. Added initial and continued criteria that use does not exceed 1 tablet per day. (Initial already had it as a QL but added to criteria for approval section) References Updated	6/16
Annual Review, No Changes	03/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file