Clinical Policy: Febuxostat (Uloric)

Reference Number: PA.CP.PMN.57
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
Febuxostat (Uloric®) is a xanthine oxidase inhibitor.

FDA approved indication
Uloric is indicated for the chronic management of hyperuricemia in patients with gout.

Limitation of use: Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Uloric is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hyperuricemia (must meet all)**:**

1. Diagnosis of gout with hyperuricemia;
2. Current (within the last 30 days) serum urate ≥ 6 mg/dL;
3. Age ≥ 18 years;
4. Member is not being concomitantly treated with azathioprine or mercaptopurine;
5. Failure of urate-lowering therapy (allopurinol OR probenecid) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 80 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Hyperuricemia (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy (e.g., reduced frequency of gout attacks, serum urate level < 6 mg/dL);
3. If request is for a dose increase, new dose does not exceed 80 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies ; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hyperuricemia in patients with gout	40 mg or 80 mg once daily	80 mg/day

VI. Product Availability

Tablet: 40 mg, 80 mg

VII. References

1. Uloric Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; March 2013. Available at: www.uloric.com. Accessed November 20, 2017. Khanna D, Fitzgerald JD, Khanna PJ, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. Arthritis Care Res. 2012; 64(10): 1431-1446.
2. Richette P, Doherty M, Pascual E, et al. 2016 Updated EULAR evidence-based recommendations for the treatment of gout. Ann Rhem Dis 2016; 0:1–14. doi:10.1136/annrheumdis-2016-209707.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q18 annual review: added age limit; added drug interactions with azathioprine and mercaptopurine; changed approval duration; references reviewed and updated.	03.04.18	