Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Febuxostat Step Therapy

Effective: June 9, 2026

Guideline Type	☐ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Uloric (febuxostat) is 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. Febuxostat is not recommended for the treatment of asymptomatic hyperuricemia.

Clinical Guideline Coverage Criteria

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan for patients who do not meet the step therapy criteria at the point of service.

Please refer to the table below for medications subject to this policy:

Drug	
Step-1	
allopurinol	Covered
Step-2	
febuxostat	Requires prior use of a drug on Step-1

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 medications by the plan:

Step 1: Generic medications on Step-1 are covered without prior authorization.

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

1. The patient has had a trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to Step – 2 medications covered by the plan:

Step 2: The plan may cover Step-2 medications if the following criteria are met:

1. The patient has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples

OR

2. Requesting physician has documented that the patient has a contraindication to or intolerance to all tolerate Step-1 medications

Note: The plan may cover medications on Step-2 if a patient has received a non-formulary medication, containing the same therapeutic ingredient as a lower step agent, as evidenced by physician documented use

Limitations

- Step therapy point of service coding does not apply to any non-formulary medications.
- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.

Codes

None

References

1. Becker MA, Schumacher RH, Wortman RL, et al. Febuxostat compared with allopurinol in patients with hyperuricemia and gout. *N Engl J Med*. 2005;353:2450-61.
2. Bruce SP. Febuxostat: A selective xanthine oxidase inhibitor for the treatment of hyperuricemia and gout. *Ann Pharmacother*. 2006;40:2187-94.
3. Choi HK, Mount DB, Reginato Am. Pathogenesis of gout. *Ann Intern Med*. 2005;143:499-516.
4. Edwards LN. Arthritis & Rheumatism. *Arthiritis Rheum*. 2008;58:2587-90.
5. Eggebeen AT. Gout: An update. *Am Fam Physician*. 2007;76:801-8.
6. Ernst, ME, Fravel, MA. Febuxostat: a selective xanthine-oxidase/xanthine-dehydrogenase inhibitior for the management of hyperuricemia in adults with gout. *Clin Ther*. 2009 Nov;31(11):2503-18.
7. Garcia-Valladares, I, Khan, T, Espinoza, LR. Efficacy and safety of febuxostat in patients with hyperuricemia and gout. *Ther Adv Musculoskelet Dis*. 2011 Oct;3(5):245-53.
8. Hamburger, M, Baraf, HS, Adamson, TC 3rd, et al. 2011 Recommendations for the diagnosis and management of gout and hyperuricemia. *Postgrad Med.* 2011 Nov;123(6 Suppl 1):3-36.
9. Keith MP, Gilliland WR. Updates in the management of gout. *Am J Med*. 2007;120:221-4.
10. Kim KY, Wigle PR. Febuxostat: A novel, non-purine xanthine oxidase inhibitor. *J Pharm Technol*. 2006;22:342-8.
11. Naoyuki, K, Shin, F, Toshikazu, H, et al. An allopurinol-controlled, multicenter, randomized, open-label, parallel between-group, comparative study of febuxostat (TMX-67), a non-purine-selective inhibitor of xanthine oxidase, in patients with hyperuricemia including those with gout in Japan: phase 2 exploratory clinical study. *J Clin Rheumatol.* 2011 Jun;17(4 Suppl 2):S44-9.
12. Schumacher RH, Becker MA, Wortmann RL, et al. Effects of febuxostat versus allopurinol and placebo in reducing serum urate in subjects with hyperuricemia and gout: A 28-week, phase III, randomized, double-blind, parallel-group trial. *Arthritis Rheum*. 2008;59:1540-8.
13. Sundy JS. Gout management: Let's get it right this time. *Arthritis Rheum*. 2008;59:1535-7.
14. Uloric (febuxostat) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2024.
15. Zhang, W, Doherty, M, Pascual, E, et al. EULAR evidence based recommendations for gout. Part II: Management. Report of a task force of the EULAR standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). *Ann Rheum Dis*. 2006 October;65(10):1312–24.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2023: No changes
- June 11, 2024: No changes
- June 10, 2025: No changes
- June 9, 2026: No clinical changes. Administrative update to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a

Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.