Pharmacy Medical Necessity Guidelines: Uloric® (febuxostat)

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

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

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then 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 prior authorization requests to the plan using the Universal Pharmacy Medical Review Request Form for members who do not meet the step therapy criteria at the point of service.

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

Drug	Tufts Health Plan Large Groups	Tufts Health Plan Small Groups and Individual Plans	Tufts Health Together and Tufts Health RITogether
Step-1			
allopurinol	Covered	Covered	Covered
Step-2			
febuxostat	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2
Step-3			
Uloric	Requires prior use of a drug on Step-2 or Step-3	Non-covered	Non-covered

Automated Step Therapy Coverage Criteria

The following stepped approach applies to Uloric (febuxostat) coverage 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 Member 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

Step 3: The plan may cover medications on Step-3 if the following criteria are met:

2. The Member has had a trial of a Step-2 or Step-3 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan

Coverage Criteria for Members 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 Member 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. The Member has a physician documented contraindication or intolerance to all Step-1 medications

The following stepped approach applies to Step-3 medications covered by the plan:

Step 3: The plan may cover Step-3 medications if the following criteria are met:

1. The Member has had a trial of a Step-2 or Step-3 medication as evidenced by physician documented use, excluding the use of samples

OR

2. The Member has a physician documented contraindication or intolerance to all Step-1 and Step-2 medications

LIMITATIONS

- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- The plan does not authorize coverage of noncovered medications through this step therapy program. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives and submit a formulary exception request to Tufts Health Plan, as indicated.

CODES

None

REFERENCES

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14. Uloric (febuxostat) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; February 2019.
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 HISTORY

November 9, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 5, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
- November 15, 2011: No changes
- June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
- November 6, 2012: Added use of samples or vouchers/coupons for brand name medications limitation
- October 15, 2013: No changes
- April 1, 2014: Administrative Update: Removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI Formulary.
- October 7, 2014: No changes
- October 6, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- October 18, 2016: No changes. Effective November 7, 2016 Medical Necessity Guideline applies to Tufts Health Together.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- October 17, 2017: Administrative update- edited the overview section. The title of the table under Coverage Guidelines was edited to read "Tufts Health Together and Tufts Health RITogether".
- October 16, 2018: No changes
- August 13, 2019: Effective January 1, 2020, added Step-3 criteria for Commercial Large group plans for brand Uloric. Brand Uloric will be moved to non-covered status effective January 1, 2020 for all Commercial Small Group and Direct plans and immediately for MA Together and RITogether plans, due to launch of generic. Updated step therapy criteria to require trial and failure with or contraindication to all medications on a lower step for approval. Added the limitation for non-covered medications referring requestor to Non-covered Drugs with Suggested Alternatives MNG.
- November 10, 2020: Administrative update to the overview section.

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.