Febuxostat (Uloric)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Management for the prevention of recurrent gout flares and damage to joints and other tissues from urate crystal deposition includes drug therapy with the xanthine oxidase inhibitors allopurinol and febuxostat, lifestyle modifications, and other strategies for risk reduction. The use of urate-lowering drugs for the prevention of recurrent gout flares and disease progression is strongly recommended. Allopurinol is first line therapy for treatment and prevention of gout flares. Allopurinol should be started at 100mg per day and titrated to a dose of 600-800mg per day or the maximally tolerated dose to achieve maximum urate lowering effect. Allopurinol dosing should be reduced if patients have renal impairment. Allopurinol also should not be started if a patient is positive for the HLA-B*5801 allele.

Febuxostat (Brand Name: Uloric) should be initiated after patients fail or have a contraindication to allopurinol dosed at 600-800mg per day. Febuxostat is FDA approved for treating hyperuricemia to prevent gout flares and should not be used for the acute gout flare treatment. Febuxostat is taken as a 40 mg tablet once daily and may be increased to 80 mg once daily. While it is mainly used for gout,

febuxostat also has evidence for use in preventing high uric acid levels after chemotherapy. It may be used to prevent a serious medical emergency called tumor lysis syndrome when allopurinol is not a good option.

Definitions

"**Gout**" is a condition where uric acid crystallizes and deposits in joints causing pain, redness, and swelling.

"**Gout Flare**" is a painful and disabling inflammatory arthritis caused by uric acid that usually involves a single joint but occasionally involves two or more joints.

"**Gout Tophi**" are caused by uric acid building up around joints. Tophi often look like swollen, bulbous growths around joints just under the skin.

"**Hyperuricemia**" is an elevated uric acid level in the blood.

"Tumor Lysis Syndrome" is a dangerous medical emergency that can happen after chemotherapy, when cancer cells break down and release its contents into the bloodstream.

"**Xanthine oxidase inhibitors**" are any substance that inhibits the activity of xanthine oxidase, an enzyme involved in purine metabolism. Inhibition of xanthine oxidase reduces the production of uric acid in the body

Clinical Indications

Medical Necessity Criteria for Initial Authorization

The Plan considers **febuxostat (Uloric)** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

Gout:

1. The member is at least 18 years of age; ***AND***
2. The requested medication is being used for long-term management of hyperuricemia (i.e., not for treatment of acute attacks); ***AND***
3. The member has documented evidence of **ONE** (1) of the following:
    a. 1 or more subcutaneous tophi***; or***

b. evidence of radiographic damage (e.g., gouty bone erosion) attributable to gout***; or***
c. frequent gout flares (defined as 2 or more per year)***; or***
d. has experienced more than 1 flare but have infrequent flares (fewer than 2 per year)***; or***
e. is experiencing first flare with comorbid moderate-to-severe chronic kidney disease (stage 3 or higher), serum urate concentration greater than 9 mg/dL, or urolithiasis; ***AND***

4. The member has documentation of hyperuricemia demonstrated by a baseline (pre-treatment) serum uric acid level greater than or equal to (≥) 6.8 mg/dL; ***AND***
5. The member is unable to use or has adequately tried and failed at least a one-month (1) trial with allopurinol dosed at 600 mg - 800 mg per day; ***AND***
6. Chart documentation and supporting labwork are provided for review to substantiate the above listed requirements.

Tumor lysis syndrome, prevention:

1. The member is at least 18 years of age***; AND***
2. The member is at intermediate or high risk for tumor lysis syndrome (e.g., the member has leukemia, lymphoma, or solid tumor malignancies and is undergoing chemotherapy expected to result in tumor lysis and subsequent elevations of serum and urinary uric acid concentrations)***; AND***
3. The member is unable to use or has tried and failed allopurinol***; AND***
4. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, febuxostat (Uloric) will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if there is chart documentation showing **ONE** (1) of the following since the member started therapy with febuxostat (Uloric):

1. Clinical remission or therapeutic benefit (e.g., cessation of gout flares, resolution of tophi, or improvement in patient physical function and health-related quality of life)***; OR***
2. A reduction or normalization of laboratory evidence of hyperuricemia or TLS (e.g., serum uric acid, serum lactate dehydrogenase)***; OR***
3. An avoidance of or reduction in metabolic complications and morbidity associated with tumor lysis syndrome, or the need for additional renal support (dialysis or hemofiltration).

Experimental or Investigational / Not Medically Necessary

febuxostat (Uloric) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

Original Date: 11/05/2020
Reviewed/Revised: 10/14/2021, 12/01/2021, 9/15/2022, 9/21/2023, 12/19/2024