MEDICAL MUTUAL®

Drug Policy

Policy:	**Gout Medications** **Preferred Step Therapy Policy**	**Annual Review Date:** **02/20/2024** **Last Revised Date:** **02/20/2024**

OVERVIEW

Gout symptoms are characterized by attacks, tophi, joint destruction, uric acid lithiasis, and/or nephropathy in the presence of hyperuricemia. Pharmacologic drug classes predominately used for the treatment of gout include xanthine oxidase inhibitors (allopurinol [Zyloprim, generics], Uloric) and uricosuric agents (probenecid). The American College of Rheumatology (ACR) guidelines (2012) for the management of gout recommend xanthine oxidase inhibitors, either allopurinol or Uloric (without preference), as first-line pharmacologic urate-lowering therapies (ULT). Serum urate level should be lowered sufficiently to improve the signs and symptoms of gout, with the target level < 6 mg/dL at a minimum. Probenacid is recommended as an alternative first-line pharmacologic therapy if the patient had intolerance or contraindications to either allopurinol or Uloric; however, it is not recommended as first-line monotherapy in patients with CrCl < 50 mL/min. Combination therapy with one xanthine oxidase inhibitor and one uricosuric agent is appropriate when the target serum urate levels have not been achieved by a xanthine oxidase inhibitor alone.

POLICY STATEMENT

A step therapy program has been developed to encourage use of one Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Step 1: allopurinol (Zyloprim) tablets
Step 2: generic febuxostat tablets

PREFERRED STEP THERAPY CRITERIA

Exceptions for generic febuxostat can be made for those who have met one of the following criteria:

1. If a patient has tried a Step 1 agent (allopurinol), then approve generic febuxostat tablets (Step 2).

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2. An exception for generic febuxostat can be made if the patient is receiving concomitant medications that have significant drug-drug interactions with allopurinol, which are not noted with generic febuxostat tablets [e.g., cyclosporine, chlorpropamide].

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

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The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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