

Pharmacy Policy Bulletin

Title: Antigout Agents
Policy #: Rx.01.192

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for **lesinurad (Zurampic®)** and **lesinurad-allopurinol (Duzallo®)** as provided under the member's prescription drug benefit.

▶ **Description:**

Gout is a disease of urate crystal deposition. In order for the signs and symptoms of gout to be present, extracellular fluid must be saturated with urate and urate crystal deposition and inflammatory responses to crystal deposition must be present. Gouty arthritis is typically managed with lifestyle modifications and risk reduction strategies combined with pharmacologic therapy.

Pharmacologic options for treating hyperuricemia associated with gout include xanthine oxidase inhibitors (allopurinol, febuxostat), probenecid, and lesinurad. Colchicine and non-steroidal anti-inflammatory drugs are typically reserved for acute gout flares and short term use.

Lesinurad inhibits uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4), resulting in decreased reabsorption of uric acid by the kidney. Allopurinol inhibits xanthine oxidase, preventing the conversion of xanthine to uric acid

Lesinurad is indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.

▶ **Policy:**

Lesinurad (Zurampic®) or Lesinurad-Allopurinol (Duzallo®) is approved when ALL of the following are present:

1. Diagnosis of gout

AND

2. Inadequate response to xanthine oxidase inhibitor monotherapy (i.e. allopurinol, Uloric®), evidenced by BOTH of the following:
 - a. Two or more gout flares in 12 months; AND
 - b. Persistently elevated serum uric acid levels greater than 6mg/dL

AND

3. Used in combination with xanthine oxidase inhibitor (applies to Zurampic® only)

▶ **Black Box Warning as shown in the drug Prescribing Information:**

RISK OF ACUTE RENAL FAILURE, MORE COMMON WHEN USED WITHOUT A XANTHINE OXIDASE INHIBITOR

Acute renal failure has occurred with lesinurad and was more common when lesinurad was given alone.

Lesinurad should be used in combination with a xanthine oxidase inhibitor.

▶ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ **References:**

Becker MA. Prevention of recurrent gout: pharmacologic urate-lowering therapy and treatment of tophi. UpToDate. Available at: https://www.uptodate.com/contents/prevention-of-recurrent-gout-pharmacologic-urate-lowering-therapy-and-treatment-of-tophi?source=search_result&search=lesinurad&selectedTitle=4~6#H2373041. Accessed January 17, 2019..

Zurampic® (lesinurad) [package insert]. Wilmington, DE. AstraZeneca. January 2018. Available at: http://irwdpi.com/zurampic/ZURAMPIC_PI_and_Medguide_2017.pdf#page=1. Accessed on January 16, 2019.

Duzallo® (lesinurad and allopurinol) [package insert]. Cambridge, MA. AstraZeneca and Ironwood Pharmaceuticals. November 2017. Available at <https://www.irwdpi.com/duzallo/DuzalloPIandMedguide2017.pdf#page=1>. Accessed on January 16, 2019.

Jones G et al. Guideline development for the management of gout: role of combination therapy with a focus on lesinurad. Drug Des Devel Ther. 2017 Oct 24; 11:3077-3081.

Applicable Drugs:

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand name	Generic name
Zurampic®	Lesinurad
Duzallo®	Lesinurad and allopurinol

Cross References:

N/A

Policy Version Number:	4.00
P&T Approval Date:	January 10, 2019
Policy Effective Date:	April 01, 2019
Next Required Review Date:	January 10, 2020

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.