

### Clinical Pharmacy Program Guidelines for Gout

Program	Prior Authorization
Medication	Zurampic <sup>®</sup> (lesinurad), Duzallo (lesinurad/allopurinol)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	12/2017
Effective Date	2/2018

**1. Background:**

Zurampic (lesinurad) is a URAT<sub>1</sub> inhibitor indicated in combination with a xanthine oxidase inhibitor [e.g. allopurinol (generic Zyloprim)] 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. Zurampic is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy.

Duzallo (lesinurad/allopurinol) is a combination URAT<sub>1</sub> inhibitor (lesinurad) and xanthine oxidase inhibitor (allopurinol) indicated for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone.

**2. Coverage Criteria:**

<p><b>A. <u>Initial Authorization</u></b></p> <p>1. <b>Zurampic</b> will be approved based on <b>all</b> of the following criteria:</p> <p style="padding-left: 40px;">a. Diagnosis of hyperuricemia associated with gout</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">b. Used in combination with a xanthine oxidase inhibitor [e.g. allopurinol (generic Zyloprim), Uloric*]</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">c. Patient has not achieved target serum uric acid levels with xanthine oxidase inhibitor monotherapy</p> <p style="text-align: center;"><b>-AND-</b></p>
---

d. Not used for the treatment of asymptomatic hyperuricemia

**Authorization will be issued for 12 months.**

2. **Duzallo** will be approved based on all of the following criteria:

a. Diagnosis of hyperuricemia associated with gout

**-AND-**

b. Patient has not achieved a target serum uric acid level with allopurinol monotherapy.

**-AND-**

c. Not used for the treatment of asymptomatic hyperuricemia

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Zurampic** will be approved based on both of the following criteria:

a. Documentation of positive clinical response to therapy

**-AND-**

b. Used in combination with a xanthine oxidase inhibitor [e.g. allopurinol (generic Zyloprim), Uloric\*]

**Authorization will be issued for 12 months.**

2. **Duzallo** will be approved based on all of the following criterion:

a. Documentation of positive clinical response to therapy

**Authorization will be issued for 12 months.**

\*Step therapy may apply

**3. References:**

1. Zurampic (prescribing information). AstraZeneca Pharmaceuticals LP. Wilmington, DE. February 2016.
2. Duzallo (prescribing information). AstraZeneca Pharmaceuticals LP. Wilmington, DE. November 2017.

Program	Prior Authorization
<b>Change Control</b>	
Date	Change
5/2016	New program
5/2017	Annual review. Updated policy template. No changes to clinical criteria.
12/2017	Added criteria for Duzallo. Changed name of policy to Gout since it now includes more than one agent.