RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Lesinurad (Zurampic®), Lesinurad/Allopurinol (Duzallo)**
Policy Number: **RxA.231**
Drug(s) Applied: **Lesinurad (Zurampic®)**
Last Review Date: **04/2020**
Line of Business: **Commercial, HIM, Medicaid**

Background

Lesinurad (Zurampic®) is a uric acid transporter 1 (URAT1) inhibitor and reduces serum uric acid levels by inhibiting the function of transporter proteins involved in uric acid reabsorption in the kidney. Duzallo is a combination of lesinurad and allopurinol, a xanthine oxidase inhibitor.

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.

Duzallo is 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.

Limitation(s) of use:
Zurampic and Duzallo are not recommended for the treatment of asymptomatic hyperuricemia. Zurampic should not be used as monotherapy.

Drug Name	Dosing Regimen	Maximum Dose
Lesinurad (Zurampic)	200 mg PO QD in combination with a xanthine oxidase inhibitor	200 mg/day
Lesinurad-allopurinol (Duzallo)	One tablet PO QD	200 mg lesinurad/ 300 mg allopurinol/day

Drug Name	Availability
Lesinurad (Zurampic)	Tablets: 200 mg
Lesinurad-allopurinol (Duzallo)	Tablets: 200 mg lesinurad/200 mg allopurinol, 200 mg lesinurad/300 mg allopurinol

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Hyperuricemia (must meet all)**:**

1. Diagnosis of hyperuricemia associated with gout;
2. Failure of allopurinol or Uloric® at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Uloric*
3. For Zurampic requests: Prescribed as combination therapy with allopurinol or Uloric;
4. Dose does not exceed 200 mg lesinurad/day.

Approval duration:
Medicaid/HIM – 12 months

Commercial – Length of Benefit

II. Continued Therapy

A. Hyperuricemia (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 200 mg lesinurad/day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

III. Appendices

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
URAT1: Uric Acid Transporter 1

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
allopurinol (Aloprim®, Zyloprim®)	Gout: (mild) 100 to 300 mg/day PO as a single or divided dose (2-3 times daily) Gout: (moderate to severe) 400 to 600 mg/day PO as a single or divided dose (2-3 times daily)	800 mg/day
Uloric (febuxostat)	40 mg PO QD; may be increased to 80 mg QD if serum uric acid levels are not less than 6 mg/dL after 2 weeks	80 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
Contraindication(s):

- Severe renal impairment (eCLcr less than 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis
- Tumor lysis syndrome or Lesch-Nyhan syndrome
- Duzallo only: known hypersensitivity to allopurinol, including previous occurrence of skin rash

Boxed warning(s): Acute renal failure has occurred with lesinurad and was more common when lesinurad was given alone, compared to combination use with a xanthine oxidase inhibitor (e.g., allopurinol, Uloric).

Appendix D: General Information
Examples of positive response to therapy include reduced frequency of gout attacks and/or serum urate level < 6 mg/dL.

References

1. Zurampic Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2018. Available at: www.zurampic.com. Accessed April 30, 2020.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 30, 2018.
3. Duzallo Prescribing Information. Cambridge, MA: AstraZeneca Pharmaceuticals LP; November 2017. Available at: www.duzallo.com. Accessed April 30, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Defined severe renal impairment as eCLcr less than 30 mL/min Updates References	4/30/2020	5/21/2020