

Clinical Policy: Lesinurad (Zurampic), Lesinurad/Allopurinol (Duzallo)

Reference Number: CP.PMN.150

Effective Date: 11.16.16

Last Review Date: 02.21

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

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.

FDA Approved Indication(s)

Zurampic 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.

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation[®] that Zurampic and Duzallo are **medically necessary** when the following criteria are met:

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 clinically significant adverse effects are experienced or both are contraindicated;
**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 (1 tablet) per day.

Approval duration:

Medicaid/HIM – 12 months

Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Hyperuricemia (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters:
 - a. Reduced frequency of gout attacks;
 - b. Serum urate level < 6 mg/dL;
3. If request is for a dose increase, new dose does not exceed 200 mg lesinurad (1 tablet) per day.

Approval duration:

Medicaid/HIM – 12 months

Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

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 [®]) | <u>Gout: (mild)</u> 100 to 300 mg/day PO as a single or divided dose (2-3 times daily) <u>Gout: (moderate to severe)</u> 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, 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).

V. Dosage and Administration

| 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 |

VI. Product Availability

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

VII. References

1. Zurampic Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2018. Available at: www.zurampic.com. Accessed November 16, 2020.
2. DRUGDEX[®] System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 16, 2020.
3. Duzallo Prescribing Information. Cambridge, MA: AstraZeneca Pharmaceuticals LP; November 2017. Available at: www.duzallo.com. Accessed November 16, 2020.

4. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care & Research*. June 2020; 0 (0): 1-17.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|--|----------|-------------------|
| Converted to new template. Minor changes to verbiage and grammar. References updated. | 01.12.17 | 11.17 |
| Per SDC, added Duzallo to criteria. | 04.12.18 | |
| 3Q 2018 annual review: replaces commercial policy, CP.CPA.174; no significant changes; Medicaid line of business added; references reviewed and updated. | 04.30.18 | 08.18 |
| 1Q 2019 annual review: no significant changes; references reviewed and updated. | 10.30.18 | 02.19 |
| HIM line of business added. | 5.21.19 | 08.19 |
| 1Q 2020 annual review: no significant changes; references reviewed and updated. | 10.29.19 | 02.20 |
| 1Q 2021 annual review: no significant changes; Appendix D deleted and added examples of positive response to section II; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated. | 11.16.20 | 02.21 |

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.