



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/15/2016
LAST REVIEW DATE: 8/20/2020
LAST CRITERIA REVISION DATE: 8/20/2020
ARCHIVE DATE:

DUZALLO™ (lesinurad and allopurinol) oral ZURAMPIC® (lesinurad) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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ZURAMPIC® (lesinurad) oral

Criteria:

- **Criteria for initial therapy:** Duzallo (lesinurad/allopurinol) and Zurampic (lesinurad) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual must be 18 years of age or older
 2. A confirmed diagnosis of symptomatic hyperuricemia associated with gout
 3. Serum uric acid level is ≥ 6.5 mg/dL on at least 3 months of xanthine oxidase inhibitor alone
 4. **Additional item for Zurampic only, ALL of the following:**
 - a. Individual has failure, contraindication or intolerance to maximally tolerated and renal adjusted doses of **2 oral xanthine oxidase inhibitors:**
 - i. Allopurinol
 - ii. Uloric (febuxostat)
 - b. A xanthine oxidase inhibitor must be used simultaneously with Zurampic
 - c. Zurampic will not be used simultaneously with Duzallo
 5. **Additional item for Duzallo only, ALL of the following:**
 - a. Individual has failure, contraindication or intolerance to renal adjusted doses of allopurinol (200 mg or 300 mg)
 - b. Individual has medical record documentation of being unable to adhere with use of renal adjusted doses of allopurinol (200 mg or 300 mg) **AND** Zurampic used at the same time
 - c. Duzallo will not be used simultaneously with Zurampic
 6. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Estimated creatinine clearance is ≥ 45 mL/min
 7. Does not have severe hepatic impairment (Child-Pugh Class C)
 8. There are **NO** contraindications
 - a. Contraindications include:
 - i. Severe renal impairment (eCrCl < 30 mL/min)
 - ii. End stage renal disease (ESRD)
 - iii. Dialysis patients
 - iv. Kidney transplant recipients
 - v. Tumor lysis syndrome
 - vi. Lesch-Nyhan syndrome

Initial approval duration: 6 months

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- **Criteria for continuation of coverage (renewal request):** Duzallo (lesinurad/allopurinol) and Zurampic (lesinurad) is considered **medically necessary** and will be approved with documentation of **ALL** of the following:
1. Individual's condition responded while on therapy
 - a. Response is defined as:
 - i. Achieved and maintains uric acid levels < 6.5 mg/dL
 - ii. Achieved and maintains a reduction in gout flares
 2. Individual has been adherent with the medication
 3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use, such as:
 - a. Contraindications as listed in the criteria for initial therapy section listed above
 - b. Significant adverse effect such as:
 - i. Uric acid nephropathy
 - ii. Kidney dysfunction
 - iii. Allopurinol induced rash/severe hypersensitivity
 - iv. Allopurinol induced hepatotoxicity
 - v. Allopurinol induced bone marrow suppression
 4. Estimated creatinine clearance is ≥ 45 mL/min
 5. Additional item for Zurampic only: continues to be used with a xanthine oxidase inhibitor
 6. Zurampic will not be used simultaneously with Duzallo
 7. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Zurampic (lesinurad) is **indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.** Zurampic (lesinurad) is not recommended for the treatment of asymptomatic hyperuricemia and it should not be used as monotherapy. Duzallo (lesinurad and allopurinol) **inhibitor for the treatment of hyperuricemia associated with gout who have not achieved target serum uric acid levels with allopurinol (a xanthine oxidase inhibitor) alone.** Duzallo (lesinurad and allopurinol) is not recommended for the treatment of asymptomatic hyperuricemia.

Failure to take lesinurad with a xanthine oxidase inhibitor may increase the risk of renal adverse events. Xanthine oxidase inhibitors include allopurinol and Uloric (febuxostat).

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Lesinurad is a urate transporter 1 (URAT1) inhibitor that reduces serum uric acid concentrations by inhibiting the function of 2 transporter proteins involved in uric acid reabsorption in the kidney: uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4). Lesinurad inhibited the function of two apical transporters responsible for uric acid reabsorption, uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4). URAT1 is responsible for the majority of the reabsorption of filtered uric acid from the renal tubular lumen. OAT4 is a uric acid transporter associated with diuretic-induced hyperuricemia. Lesinurad does not interact with the uric acid reabsorption transporter SLC2A9 (Glut9), located on the basolateral membrane of the proximal tubule cell.

Allopurinol reduces the production of uric acid by inhibiting the biochemical reactions involved in uric acid formulation. Allopurinol is an inhibitor of xanthine oxidase, the enzyme that is responsible for conversion of hypoxanthine to xanthine and of xanthine to uric acid. Allopurinol is metabolized to oxypurinol which is also a xanthine oxidase inhibitor.

Definitions:

Allopurinol dose adjustments for kidney dysfunction:

| Creatinine Clearance (mL/min) | Daily Dose |
|-------------------------------|-------------------------|
| > 20 | 300 up to max of 800 mg |
| 10-20 | 200 mg |
| < 10 | 100 mg |

| Alternative Dosage Adjustment† | |
|--------------------------------|---------------------------------------|
| Creatinine Clearance (mL/min) | Dose(milligrams) / Interval |
| 140 | 400 mg/day, up to max dose 800 mg/day |
| 120 | 350 mg/day |
| 100 | 300 mg/day |
| 80 | 250 mg/day |
| 60 | 200 mg/day |
| 40 | 150 mg/day |
| 20 | 100 mg/day |
| 10 | 100 mg/every 2 days |
| 0 | 100 mg/every 3 days |

† Micromedex: Allopurinol dose adjustment

Resources:

Zurampic (lesinurad). Package Insert. Revised by manufacturer 01/2018. Accessed 09-12-2016, 08-28-2017, 07-19-2018, 06-16-2020

Duzallo (lesinurad and allopurinol) Package Insert. Revised by manufacturer 11/2017. Accessed 06-16-2020

Micromedex® 2.0, (Allopurinol accessed electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/> (cited: September 14, 2016).



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UpToDate: Prevention of recurrent gout: Pharmacologic urate-lowering therapy and treatment of tophi. Current through Aug 2017

UpToDate: Pharmacologic urate-lowering therapy and treatment of tophi in patients with gout. Current through Jul 2018

UpToDate: Treatment of gout flares. Current through Jul 2018
