Zurampic

Description

Zurampic (lesinurad)

Background
Zurampic is a URAT1 (uric acid transporter 1) inhibitor indicated for the treatment of hyperuricemia associated with gout in adults who do not respond to conventional therapy. Zurampic works by helping the kidney excrete uric acid. It does this by inhibiting the function of transporter proteins involved in uric acid reabsorption in the kidney (1).

Regulatory Status
FDA-approved indication: Zurampic is a URAT1 inhibitor 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 (1).

Limitations of Use: (1)
Zurampic is not recommended for the treatment of asymptomatic hyperuricemia. Zurampic should not be used as monotherapy.

Zurampic carries a boxed warning for risk of acute renal failure. Zurampic should only be used in combination with a xanthine oxidase inhibitor. Zurampic should not be initiated in patients with an estimated creatinine clearance (eCrCl) less than 45 mL/min. Assessment of renal function is recommended prior to initiation of Zurampic therapy and periodically thereafter. More frequent renal function monitoring is recommended in patients with an eCLcr below 60 mL/min. Zurampic should be discontinued when eCLcr is persistently less than 45 mL/min (1).
Zurampic is contraindicated in the following conditions (1):

- Severe renal impairment (eCrCl less than 30 mL/min), end stage renal disease (ESRD), kidney transplant recipients, or patients on dialysis.
- Tumor lysis syndrome or Lesch-Nyhan syndrome.

The safety and effectiveness of Zurampic in pediatric patients less than 18 years of age have not been established (1).

**Related policies**

Duzallo, Krystexxa, Uloric

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Zurampic may be considered *medically necessary* in patients that are 18 years of age and older for the treatment of chronic symptomatic gout and if the conditions indicated below are met.

Zurampic may be considered *investigational* in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age and older

**Diagnosis**

Patient must have the following:

1. Chronic gout

**AND ALL** of the following:

a. Symptomatic
b. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
i. Allopurinol (Zyloprim)
ii. Probenecid
c. Used in combination with xanthine oxidase inhibitor
d. Estimated creatinine clearance (eCrCl) greater than 45 mL/min

AND NONE of the following:
   a. Severe renal impairment, ESRD, kidney transplant or on dialysis
   b. Tumor lysis syndrome
   c. Lesch-Nyhan syndrome
   d. Dual therapy with Duzallo

Prior – Approval Renewal Requirements

Age        18 years of age and older

Diagnosis

Patient must have the following:

1. Chronic gout

   AND ALL of the following:
   a. Improvement in symptoms
   b. Used in combination with xanthine oxidase inhibitor
   c. Estimated creatinine clearance (eCrCl) greater than 45 mL/min

   AND NONE of the following:
   a. Severe renal impairment, ESRD, kidney transplant or on dialysis
   b. Tumor lysis syndrome
   c. Lesch-Nyhan syndrome
   d. Dual therapy with Duzallo

Policy Guidelines

Pre - PA Allowance

None
Prior - Approval Limits

Quantity  200mg  90 tablets per 90 days
Duration  6 months

Prior – Approval Renewal Limits

Quantity  200mg  90 tablets per 90 days
Duration  12 months

Rationale

Summary
Zurampic is approved for the treatment of chronic symptomatic gout in adult patients who are refractory to conventional therapy. Patients should be closely monitored for anaphylaxis after administration of Zurampic. Serum uric acid levels should be monitored prior to infusions and therapy should be discontinued if levels increase to above 6mg/dL (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Zurampic while maintaining optimal therapeutic outcomes.

References

Policy History

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<td>February 2016</td>
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March 2019 Annual review and reference update. Revised requirement to trial of allopurinol or probenecid

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.