Duzallo

Description

Duzallo (lesinurad and allopurinol)

Background
Duzallo is a combination drug containing lesinurad, a URAT1 (uric acid transporter 1) inhibitor, and allopurinol, a xanthine oxidase inhibitor, indicated for the treatment of hyperuricemia associated with gout in adults who do not respond to conventional therapy. Duzallo is a dual-mechanism treatment option to help patients with uncontrolled gout achieve target serum uric acid levels. Lesinurad 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. Allopurinol reduces the production of uric acid (1).

Regulatory Status
FDA-approved indication: Duzallo a combination of lesinurad, a URAT1 inhibitor, and allopurinol, a xanthine oxidase inhibitor, 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 (1).

Limitations of Use: (1)
Duzallo is not recommended for the treatment of asymptomatic hyperuricemia.

Duzallo carries a boxed warning for risk of acute renal failure. Duzallo 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 Duzallo therapy and periodically thereafter.
More frequent renal function monitoring is recommended in patients with an eCrCl below 60 mL/min. Duzallo should be discontinued when eCrCl is persistently less than 45 mL/min (1). Duzallo 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
- Known hypersensitivity to allopurinol, including previous occurrence of skin rash

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

Related policies
Krystexxa, Uloric, Zurampic

Policy

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

Duzallo 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.

Duzallo 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:

Chronic gout

AND ALL of the following:
1. Symptomatic
2. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
   a. Allopurinol (Zyloprim)
   b. Probenecid

3. Estimated creatinine clearance (eCrCl) greater than 45 mL/min

**AND** **NONE** of the following:
1. Severe renal impairment, ESRD, kidney transplant or on dialysis
2. Tumor lysis syndrome
3. Lesch-Nyhan syndrome
4. Hypersensitivity to allopurinol
5. Dual therapy with Zurampic

**Prior – Approval Renewal Requirements**

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

Chronic gout

**AND ALL** of the following:
1. Improvement in symptoms
2. Estimated creatinine clearance (eCrCl) greater than 45 mL/min

**AND** **NONE** of the following:
1. Severe renal impairment, ESRD, kidney transplant or on dialysis
2. Tumor lysis syndrome
3. Lesch-Nyhan syndrome
4. Hypersensitivity to allopurinol
5. Dual therapy with Zurampic

**Policy Guidelines**

**Pre - PA Allowance**
Prior - Approval Limits

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<th>Quantity</th>
<th>200/200mg</th>
<th>90 tablets per 90 days OR</th>
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Duration 6 months

Prior – Approval Renewal Limits

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Duration 12 months

Rationale

Summary
Duzallo is a dual-mechanism treatment option to help patients with uncontrolled gout achieve target serum uric acid levels. Lesinurad 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. Allopurinol reduces the production of uric acid (1).

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

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>September 2017</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>December 2017</td>
<td>Annual editorial review Addition of no dual therapy with Zurampic per SME</td>
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<tr>
<td>March 2018</td>
<td>Annual review</td>
</tr>
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March 2019 Annual review. 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.