DUZALLO
(lesinurad and allopurinol)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).
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