BlueCross BlueShield Federal Employee Program

KRYSTEXXA (pegloticase)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Krystexxa is a pegylated uric acid specific enzyme indicated for the treatment of chronic gout in adults who do not respond to (refractory) or who cannot tolerate conventional therapy. Krystexxa achieves its therapeutic effect by converting uric acid to allantoin, a water-soluble product that gets readily eliminated primarily by the kidneys decreasing serum uric acid. Krystexxa is given as an intravenous infusion every two weeks. The optimal treatment duration with Krystexxa has not been established (1).

Regulatory Status

FDA-approved indication: Krystexxa (pegloticase) is a pegylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients who are refractory to conventional therapy (1).

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated (1).

Limitations of Use:

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia (1).

Krystexxa carries a boxed warning for anaphylaxis and infusion reactions during and after administration. Krystexxa should only be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Patients should be pre-medicated with antihistamines and corticosteroids and closely monitored for anaphylaxis for an appropriate time after treatment with Krystexxa. Infusion reactions are more frequent with higher baseline uric acid levels. Serum uric acid levels should be monitored prior to infusions and discontinued if levels increase to above 6 mg/dL particularly when 2 consecutive levels above 6 mg/dL are observed (1).

Krystexxa is contraindicated in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency due to risk of hemolysis (destruction of red blood cells) and methemoglobinemia. Before starting Krystexxa, patients at higher risk for G6PD deficiency should be screened (1).

Krystexxa has not been formally studied in patients with congestive heart failure, but some patients in clinical trials experienced exacerbation of congestive heart failure. Patients with congestive heart failure should be closely monitored following infusion for exacerbation of symptoms (1).

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

Summary

Krystexxa 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 Krystexxa. 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 Krystexxa while maintaining optimal therapeutic outcomes.

References

1. Krystexxa [package insert]. Lake Forest, IL: Horizon Pharma USA, Inc.; November 2022.