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5.70.014

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	December 7, 2011
Subject:	Krystexxa	**Page:**	1 of 5

Last Review Date: June 13, 2024

Krystexxa

Description

Krystexxa (pegloticase)

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).

Related policies
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.

Krystexxa may be considered **medically necessary** if the conditions indicated below are met.

Krystexxa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Chronic gout (hyperuricemia)

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. Prescriber agrees to monitor serum uric acid levels prior to subsequent infusions and consider discontinuing treatment if levels rebound and increase to above 6 mg/dL
4. **NO** glucose-6-phosphate dehydrogenase (G6PD) deficiency

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Chronic gout (hyperuricemia)

AND ALL of the following:

1. Symptomatic
2. Documented improvement in serum uric acid level
3. **NO** glucose-6-phosphate dehydrogenase (G6PD) deficiency

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Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.

Policy History

Date	Action
December 2011	New Addition
September 2012	Annual editorial review and reference update
June 2013	Annual editorial review and reference update
June 2014	Annual editorial review and reference update
June 2015	Annual editorial review and reference update
March 2016	Annual editorial review and reference update, updated background, added criteria - Prescriber agrees to monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL.

	Policy code changed from 5.02.14 to 5.70.14
March 2017	Annual review and reference update
March 2018	Annual editorial review Added age limit and NO Glucose-6-phosphate deficiency (G6PD) to renewal section
March 2019	Annual review and reference update. Revised serum uric acid level monitoring requirement per SME. Changed requirement of trial of xanthine oxidase inhibitor to a trial of allopurinol or probenecid
March 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review and reference update
January 2023	Per FEP, changed approval and renewal duration to 12 months and changed uric acid level requirement on continuation to require documented improvement rather than specific serum uric acid value. Changed policy number to 5.70.014
March 2023	Annual review
December 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.