Clinical Policy: Pegloticase (Krystexxa®)

Reference Number: PA.CP.PHAR.115
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for pegloticase injection (Krystexxa®).

FDA Approved Indication(s)
Krystexxa is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Limitation(s) of use: Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Krystexxa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Gout (must meet all):

1. Age ≥18 years;
2. Diagnosis of chronic gout;
3. Positive for symptomatic gout with one or more of the following:
   a. ≥ 3 gout flares in the previous 18 months;
   b. ≥ 1 gout tophus;
   c. Chronic gouty arthritis;
4. Failure to normalize uric acid to < 6 mg/dL with at least 3 months each of allopurinol and febuxostat (at maximumally indicated doses) unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of one uricosuric agent (e.g., probenecid or losartan) at up to maximally indicated doses, in combination with allopurinol or febuxostat unless contraindicated or clinically significant adverse effects are experienced;
6. Has tested negative for glucose-6-phosphate dehydrogenase (G6PD) deficiency;
7. Prescribed dose does not exceed 8 mg (uricase protein) given as an intravenous infusion every two weeks.

Approval duration: 6 months

2. **Other diagnoses/indications:** Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed

B.

II. Continued Approval

A. Chronic Gout (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., demonstrated decrease in plasma uric acid levels);
3. Member is not concurrently taking any oral urate-lowering agents (e.g., allopurinol, febuxostat, probenecid);
4. If request is for a dose increase, new dose does not exceed 8 mg (uricase protein) every two weeks.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed

Background

Description/Mechanism of Action:

Krystexxa is a uric acid specific enzyme which is a PEGylated product that consists of recombinant modified mammalian urate oxidase (uricase) produced by a genetically modified strain of Escherichia coli. Krystexxa is intended for intravenous infusion. Krystexxa concentrations are expressed as concentrations of uricase protein. Krystexxa achieves its therapeutic effect by catalyzing the oxidation of uric acid to allantoin, thereby lowering serum uric acid. Allantoin is an inert and water soluble purine metabolite. It is readily eliminated, primarily by renal excretion.

Formulations:

Krystexxa is supplied as a solution intended for intravenous infusion after dilution. It is available in a single-use 2 mL glass vial with a Teflon® coated (latex-free) rubber injection stopper to deliver Krystexxa as 8 mg of uricase protein in 1 mL volume.

Appendices

Appendix A: Abbreviation Key

G6PD: glucose-6-phosphate dehydrogenase

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2507	Injection, pegloticase, 1mg

Reviews, Revisions, and Approvals	Date	Approval Date
- Added requirement to fail one uricosuric agent in combination with a xanthine oxidase inhibitor, after failure of xanthine oxidase inhibitors alone, per treatment guidelines. For continued approval, added the requirement to confirm the absence of concurrent oral urate-lowering agents. Changed approval durations from 3 and 6 months to 6 and 12 months for initial and continued approvals, respectively. References reviewed and updated.	2.18	

1. **ReferencesKrystexxa Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; September 2016. Available at: https://hznp.azureedge.net/public/KRYSTEXXA_Prescribing_Information.pdf. Accessed September 22, 2017.**
2. Khanna D, Fitzgerald, JD, Khanna PP, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia gout. *Arthritis Care Res.* October 2012; 64(10): 1431-1446.
3. Khanna D, Fitzgerald, JD, Khanna PP, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia gout. Arthritis Care Res. October 2012; 64(10): 1431-1446.