Clinical Policy: Pegloticase (Krystexxa®)

Reference Number: PA.CP.PHAR.115
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

Description
Pegloticase (Krystexxa®) is a PEGylated uric acid specific enzyme.

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. At least 3 gout flares in the previous 18 months;
   b. At least 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 Uloric® (febuxostat), at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of one uricosuric agent (e.g., probenecid or losartan) at maximally indicated doses, in combination with allopurinol or Uloric (febuxostat) unless contraindicated or clinically significant adverse effects are experienced;
6. Prescribed dose does not exceed 8 mg (uricase protein) every two weeks.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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 as evidenced by a decrease in plasma uric acid levels;

3. Member is not concurrently taking any oral urate-lowering agents (e.g., allopurinol, Uloric (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

2. 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.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
G6PD: glucose-6-phosphate dehydrogenase

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
allopurinol (Zyloprim®)	400-600 mg PO QD	600 mg/day
Uloric (febuxostat)	40 mg PO QD	80 mg/day
probenecid	500 mg PO BID	2 gm/day
losartan (Cozaar®)*	50 mg PO QD	50 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): G6PD deficiency
- Boxed warning(s): anaphylaxis and infusion reactions; G6PD deficiency-associated hemolysis and methemoglobinemia

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Chronic gout	8 mg IV every 2 weeks	8 mg/2 weeks

V. Product Availability

Vial: 8 mg of uricase protein/1 mL

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	
- 1Q 2019 annual review: removed the requirement for G6PD deficiency testing to align with the previously approved Corporate approach for G6PD deficiency testing; references reviewed and updated.	01/19	

References

1. Krystexxa Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; July 2018. Available at: https://hznp.azureedge.net/public/KRYSTEXXA_Prescribing_Information.pdf. Accessed November 6, 2018.

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. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 6, 2018.