

pegloticase (Krystexxa)**Medical Benefit Drug Policy****Place of Service**

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Drug Details**USP Category:** ANTIGOUT AGENTS**Mechanism of Action:** Pegloticase is a biosynthetic urate oxidase enzyme which catalyzes the oxidation of uric acid to allantoin, thereby lowering uric acid concentrations**HCPCS:**

J2507:Injection, pegloticase, 1 mg

How Supplied:

8 mg (single use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Chronic Gout, refractory

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria**The following condition(s) require Prior Authorization/Preservice.****Chronic Gout, refractory****Meets medical necessity if all the following are met:**

1. Patient is 18 years of age or older
2. Has a diagnosis of chronic gout as demonstrated by one of the following:
 - a. ≥ 2 gout flares annually
 - b. ≥ 1 tophus
 - c. Chronic gouty arthritis
3. Inadequate response, intolerance, or contraindication to allopurinol

Covered Doses:

Up to 8 mg given intravenously every 2 weeks

Coverage Period:

Initial: 1 year

Reauthorization: Yearly if meets all of the following:

1. Serum uric acid \leq 6mg/dL
2. Patient has been compliant with every 2-week regimen

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. FitzGerald JD, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care Res (Hoboken). 2020 Jun;72(6):744-760. doi: 10.1002/acr.24180. Epub 2020 May 11. Erratum in: Arthritis Care Res (Hoboken). 2020 Aug;72(8):1187. Erratum in: Arthritis Care Res (Hoboken). 2021 Mar;73(3):458.
4. Krystexxa (Pegloticase) Prescribing Information. Horizon Therapeutics Ireland DAC, Dublin, Ireland: 1/2025.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*