pegloticase (Krystexxa)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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 ≤ 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