

Pegloticase (Krystexxa®)

Place of Service

Office Administration
Outpatient Facility Infusion
Administration
Infusion Center Administration

HCPCS: J2507 per 1mg

Condition listed in policy (see criteria for details)

- [Chronic gout, refractory](#)

AHFS therapeutic class: Antigout agent

Mechanism of action: Pegloticase is a biosynthetic urate oxidase enzyme which catalyzes the oxidation of uric acid to allantoin, thereby lowering uric acid concentrations

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Krystexxa® (pegloticase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chronic gout, refractory

1. Patient is ≥ 18 years old, **AND**
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

AND

3. Inadequate response, intolerance, or contraindication to allopurinol

Covered Doses

Up to 8 mg IV every 2 weeks

Coverage Period

Initial: 1 year

Reauthorization: Yearly if meets the below

1. Serum uric acid ≤ 6 mg/dL, **AND**
2. Patient has been compliant with every 2-week regimen

ICD-10:

M1A

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Krystexxa® (pegloticase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

8 mg/ml solution (single-use vials)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- 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.
- Krystexxa® (Pegloticase) [Prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; 11/2022.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- Section (2): Chronic gout – Update coverage of chronic gout diagnostic criteria to include 2 or more gout flares annually

Rationale: 2020 American College of Rheumatology Guideline for the Management of Gout defines frequent gout flares as 2 or more flares annually

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*