SmartHealth Ascension

Pegloticase

(Krystexxa®) J2507 (1mg)

Covered with prior authorization

Krystexxa® (Pegloticase) may be authorized when the following criteria are met:

Chronic Gout
Individual meets ALL of the following criteria:

- Individual is 18 years of age or older; **AND**
- Individual has current symptoms of gout (for example gout flares, gout tophus, or gouty arthritis); **AND**
- Documentation of **ONE** of the following:
  - Individual has had an inadequate response, defined as serum uric acid level that remained > 6 mg/dL following a 3-month trial of **BOTH** of the following:
    - Xanthine oxidase inhibitor (allopurinol or febuxostat) used at the maximum medically appropriate dose.
      - ***Note:*** *maximum recommended dosage of allopurinol (Zyloprim) is 800 mg/day and febuxostat (Uloric) is 80 mg/day.*
    - Combination of a xanthine oxidase inhibitor and a uricosuric agent (for example, probenecid); **OR**
  - Individual has a contraindication per FDA label, significant intolerance, or is not a candidate for **BOTH** of the following:
    - Allopurinol (e.g., hypersensitivity, concomitant use of azathioprine, mercaptopurine, or theophylline)
    - Uricosuric agents [probenecid (e.g., hypersensitivity, renal insufficiency)]
      NOTE: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation; **AND**

- The medication is prescribed by, or in consultation with, a rheumatologist, nephrologist, or prescriber who specializes in gout.

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Asymptomatic Hyperuricemia.

- Known Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 6 months.

Reauthorization approval duration is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
Krystexxa® (Pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

References:
1. Krystexxa® injection [prescribing information]. Lake Forest, IL: Horizon Therapeutics; August 2022.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care Res. 2020 Jun;72(6):744-760.
3. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. JAMA. 2011;306(7):711- 720.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.