CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Krystexxa (pegloticase)
BILLING CODE	J2507
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Krystexxa (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. According to the American College of Rheumatology guideline for management of gout, pegloticase should not be a first-line therapy. Pegloticase is recommended for patients with gout for whom xanthine oxidase inhibitor treatment, uricosurics, and other interventions have failed to achieve the serum uric acid target, and who continue to have frequent gout flares or who have non-resolving subcutaneous tophi.

Krystexxa (pegloticase) will be considered for coverage when the following criteria are met:

CHRONIC GOUT

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is being prescribed by or in consultation with a gout specialist (e.g., rheumatologist, nephrologist, podiatrist, etc.); AND
3. Member has a diagnosis of chronic gout with 2 or more flares per year OR with non-resolving subcutaneous tophi associated with gout; AND
4. Member has had inadequate response (defined as serum uric acid (sUC) level remains above 6 mg/dL), or have contraindication to **both** of the following:
   a) A xanthine oxidase inhibitor (e.g., allopurinol (Zyloprim) or febuxostat (Uloric)) at maximally appropriate dose for 90 days. Note: allopurinol is first-line;
   b) A uricosuric agent (e.g., probenecid) for 90 days; AND
5. Member does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency per screening result.
6. **Dosage allowed/Quantity limit:** 1 single-dose vial (8 mg of uricase protein) given as an intravenous infusion every 2 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member's serum uric acid (sUC) level has maintained below 6 mg/dL; AND
2. Chart notes demonstrate a positive outcome from using medication (e.g. reduction of flares, reduction of tophi).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Krystexxa (pegloticase) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/06/2021	New policy for Krystexxa (pegloticase) created.

References:

1. Krystexxa [package insert]. Dublin, Ireland; Horizon Therapeutics Ireland DAC. January 2020.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in Arthritis Care Res (Hoboken). 2020 Aug;72(8):1187] [published correction appears in Arthritis Care Res (Hoboken). 2021 Mar;73(3):458]. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
3. ClinicalTrials.gov. Observational study of the use of pegloticase (Krystexxa) in refractory chronic gout. NCT 01466166.

Effective date: 10/1/2021
Revised date: 04/06/2021