TRUECARE

PHARMACY POLICY STATEMENT
Mississippi Medicaid

DRUG NAME	Krystexxa (pegloticase)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Krystexxa, approved by the FDA in 2010, 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 prescribed by or in consultation with a rheumatologist; 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 (sUA) level remains above 6 mg/dL), or contraindication to, at least 3 months of both of the following:
   a) A xanthine oxidase inhibitor (e.g., allopurinol (Zyloprim) or febuxostat (Uloric)) at maximally appropriate dose. Note: allopurinol is first-line (typically 300 to 800 mg/day) and
   b) A uricosuric agent (e.g., probenecid); AND
5. Krystexxa will be co-administered with methotrexate unless contraindicated or not tolerated; AND
6. Other urate lowering therapy (i.e., allopurinol, febuxostat, probenecid, lesinurad) will be discontinued; AND
7. Member does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency per screening result.
8. **Dosage allowed/Quantity limit:** 1 single-dose vial (8 mg) given as an intravenous infusion every 2 weeks, co-administered with weekly methotrexate 15 mg.
   QL: 2 vials per 28 days

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

For **reauthorization**:

1. Member's serum uric acid (sUA) level has maintained below 6 mg/dL; AND
2. Chart notes demonstrate a positive clinical 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.

TrueCare 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.
07/28/2022	Transferred to new template. Updated and added references. Removed nephrology, podiatry specialists. Corrected sUC to sUA. Added QL. Added must be given with methotrexate (new labeling). Added not to be used with other urate lowering drugs. Added example dosing to first line allopurinol.
01/15/2025	Consolidated references; no changes to criteria.

References:

1. Krystexxa [package insert]. Dublin, Ireland; Horizon Therapeutics Ireland DAC; 2022.
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. 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. doi:10.1001/jama.2011.1169
4. Botson JK, Tesser JRP, Bennett R, et al. Pegloticase in Combination With Methotrexate in Patients With Uncontrolled Gout: A Multicenter, Open-label Study (MIRROR). *J Rheumatol*. 2021;48(5):767-774. doi:10.3899/jrheum.200460

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