Reference number(s)
2206-A

Standard Medicare Part B Management Krystexxa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Krystexxa	pegloticase

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Krystexxa is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Limitations of Use

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions for continuation of therapy:

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Documentation (e.g., chart notes, lab test results) of a response to therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares).

Coverage Criteria

Chronic gout[1]

Authorization of 12 months may be granted for treatment of chronic gout when ALL of the following criteria are met:

- The requested medication will NOT be used concomitantly with oral urate-lowering therapies.
- The member is refractory to conventional therapy (e.g., allopurinol, febuxostat) at the maximum medically appropriate dose, or the member has a clinical reason to avoid treatment with all conventional therapies.
- The member meets one of the following criteria:
    - The requested medication will be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation, or
    - The member has a contraindication to or clinical reason to avoid oral methotrexate therapy.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member has NOT had two consecutive serum uric acid levels above 6 mg/dL since starting treatment with the requested medication.
- The member is receiving benefit from therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Krystexxa.

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- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- 2020 American College of Rheumatology guideline for the management of gout.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Krystexxa are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Krystexxa to treat chronic gout can be found in the most recent American College of Rheumatology guidelines for the management of gout. Krystexxa is not recommended as initial first-line urate lowering therapy (ULT) in patients with gout. Although there is moderate evidence for efficacy, there are concerns for cost and safety of pegloticase as well as favorable benefit-to-harm ratios of other first-line options. When xanthine oxidase inhibitors (XOI; i.e., allopurinol or febuxostat), uricosurics, and other interventions have failed to achieve serum urate (SU) target levels and the patient has frequent gout flares (2 or more per year) or has nonresolving subcutaneous tophi, switching to Krystexxa is recommended over continuing current ULT. However, if gout flares are infrequent (less than 2 per year) and no tophi are present, continuing current ULT is recommended over switching to Krystexxa.

References

1. Krystexxa [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; August 2025.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al: 2020 American College of Rheumatology guideline for the management of gout. Arthritis Care Res (Hoboken) 2020; 72(6):744-760.

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