

## **RX.PA.020.MPC Krystexxa® (Pegloticase)**

The purpose of this policy is to define the prior authorization process for Krystexxa® (pegloticase).

Krystexxa® (pegloticase) is a uric acid-specific enzyme that is indicated for the treatment of chronic gout in adult patients who are refractory to conventional therapy for chronic gout. Conventional therapies include Uloric® (febuxostat) and allopurinol.

The drug, Krystexxa® (pegloticase), is subject to the prior authorization process.

### **PROCEDURE**

#### **A. Initial Authorization Criteria:**

*Must meet all of the criteria listed below:*

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of symptomatic chronic gout defined as:
  - Baseline serum uric acid level >8mg/dL
  - At least 3 gout flares in the previous 18 months or a history of at least 1 gout tophus or of gouty arthritis
- Must have an adequate trial of TWO xanthine oxidase inhibitors with an inadequate response at maximum dosing (e.g., allopurinol 800mg/day and Uloric 80mg/day) or intolerance, unless these agents are contraindicated
  - Inadequate response is defined as the inability of these agents to normalize uric acid to less than 6mg/dL with at least 3 months of treatment
- Must not be currently receiving other urate lowering therapies (i.e. allopurinol, febuxostat, probenecid, etc.)
- Must be administered in an unregulated healthcare setting by a healthcare provider who is prepared to treat anaphylaxis

**B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**

**C. Krystexxa will be considered investigational or experimental for any other use and will not be covered.**

#### **D. Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the

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Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

**MPC Renewal:**

- Chart documentation from the prescriber that the member’s condition has improved based upon the prescriber’s assessment while on therapy (i.e. reduction of symptoms, reduction of tophi).
- Chart documentation showing that the member’s last 2 uric acid levels, prior to Krystexxa infusion, were not greater than 6mg/dL
- Chart documentation showing adherence with every 2-week dosing regimen

**Renewal from Previous Insurer:**

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has documented clinical response of the member’s condition which has stabilized or improved based upon the prescriber’s assessment (i.e. reduction of symptoms, reduction of tophi)

**Limitations:**

<b>Length of Authorization (if above criteria met)</b>	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
<b>Quantity Level Limit</b>	
Vial	2 vials per 28 days

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

**HCPSC Code(s):**

<b>Code</b>	<b>Description</b>
J2507	Injection, pegloticase, 1 mg

**REFERENCES**

1. Krystexxa [package insert]. Savient Pharmaceuticals: East Brunswick, NJ; September 2010.

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**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/2026</i>
<i>Annual review</i>	<i>02/2025</i>
<i>Annual review Change in Non-MPC renewal to renewal from previous insurer</i>	<i>02/2024</i>
<i>Annual review</i>	<i>02/2023</i>
<i>Selected Revision Addition of MPC vs Non-MPC Renewal Criteria</i>	<i>08/2022</i>
<i>Annual review</i>	<i>02/2022</i>
<i>Addition of dosing requirements and off-label restrictions</i>	<i>12/2021</i>
<i>P&amp;T Review</i>	<i>11/2020</i>