

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

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a rheumatologist
- 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 a xanthine oxidase inhibitor with an inadequate response at maximum dosing (e.g., allopurinol 800mg/day or 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 be administered in a healthcare setting by a healthcare provider who is prepared to treat anaphylaxis

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- 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

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
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):

Code	Description
J2507	Injection, pegloticase, 1 mg

REFERENCES

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