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

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

Kyrstexxa® (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, Kyrstexxa® (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. Kyrstexxa 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 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

Non-MPC Renewal:

- Members who have previously been taking Kyrstexxa and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving medication samples for Kyrstexxa; AND
- 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:

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.

HCPCS Code(s):

Code	Description
J2507	Injection, pegloticase, 1 mg

REFERENCES

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

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2023*
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*08/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*