RX.PA.020.CCH 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.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

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

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be prescribed by, or in consultation with, a rheumatologist
- Must have a diagnosis of symptomatic chronic gout defined as ONE of the following:
  - At least 2 gout flares in the previous 12 months
  - At least 1 gouty tophus
  - Chronic gouty arthritis
- Must have a baseline serum uric acid level >6 mg/dL
- Must have an adequate trial* of at least TWO of the following for at least 3 months:
  - Allopurinol (maximum dose 800 mg/day)
  - Febuxostat (maximum dose 80 mg/day)
  - Probenecid

    - *NOTE: Adequate trial is defined as a 3-month trial at the maximally tolerated dose and uric acid levels do not normalize (<6 mg/dL)
- Must have documentation or an attestation from the provider of all the following:
    - The member will not be using the requested medication with other urate lowering therapies (e.g., allopurinol, febuxostat, probenecid)
    - The member will be using the requested medication with methotrexate, unless methotrexate is not clinically appropriate
    - Krystexxa may be used as monotherapy if methotrexate is contraindicated
    - The member does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

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 of the following:

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy (e.g., reduction of symptoms, reduction of tophi, reduction in serum uric acid levels compared to baseline)
- Documentation showing the member has not had two consecutive uric acid levels >6 mg/dL while on therapy with the requested medication
- Documentation or an attestation from the provider showing the following:
    - The member has been adherent with the every 2-week dosing regimen
    - The member is not using the requested medication with other urate lowering therapies (e.g., allopurinol, febuxostat, probenecid)
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

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.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J2507	Krystexxa	INJECTION, PEGLOTICASE, 1 MG

References:

1. Krystexxa [package insert]. Savient Pharmaceuticals: East Brunswick, NJ; September 2010.
2. Krystexxa [package insert]. Horizon Therapeutics USA, Inc.: Deerfield, IL; July 2022.
3. 2020 American College of Rheumatology guideline. Wiley online library. https://onlinelibrary.wiley.com/doi/10.1002/art.41247.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	04/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior

authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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