CENTENE Corporation

Clinical Policy: Pegloticase (Krystexxa)

Reference Number: CP.PHAR.115
Effective Date: 06.01.13
Last Review Date: 02.22
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Pegloticase (Krystexxa®) is a PEGylated uric acid specific enzyme.

FDA Approved Indication(s)

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

Limitation(s) of use: Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Krystexxa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Gout (must meet all)**:**

1. Diagnosis of chronic gout;
2. Age ≥ 18 years;
3. Positive for symptomatic gout with one or more of the following:
   a. At least 3 gout flares in the previous 18 months;
   b. At least 1 gout tophus;
   c. Chronic gouty arthritis;
4. Failure to normalize uric acid to < 6 mg/dL with allopurinol and Uloric® at maximally indicated doses, each used for at least 3 months unless clinically significant adverse effects are experienced or both are contraindicated;
5. Failure of one uricosuric agent (e.g., probenecid or losartan), at maximally indicated doses, in combination with allopurinol or Uloric unless clinically significant adverse effects are experienced or all are contraindicated;
6. Krystexxa is not prescribed concurrently with oral urate-lowering agents (e.g., allopurinol, Uloric, probenecid);
7. Dose does not exceed 8 mg (uricase protein) every two weeks.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Chronic Gout (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by a decrease in plasma uric acid levels;
3. Krystexxa is not prescribed concurrently with oral urate-lowering agents (e.g., allopurinol, Uloric, probenecid);
4. If request is for a dose increase, new dose does not exceed 8 mg (uricase protein) every two weeks.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
G6PD: glucose-6-phosphate dehydrogenase

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
allopurinol (Zyloprim®)	400-600 mg PO QD	600 mg/day
Uloric (febuxostat)	40 mg PO QD	80 mg/day
probenecid	500 mg PO BID	2 gm/day
losartan (Cozaar®)*	50 mg PO QD	50 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): G6PD deficiency
- Boxed warning(s): anaphylaxis and infusion reactions; G6PD deficiency-associated hemolysis and methemoglobinemia

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Chronic gout	8 mg IV every 2 weeks	8 mg/2 weeks

VI. Product Availability

Vial: 8 mg of uricase protein/1 mL

VII. References

1. Krystexxa Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; July 2018. Available at: https://hznp.azureedge.net/public/KRYSTEXXA_Prescribing_Information.pdf. Accessed November 20, 2021.
2. Khanna D, Fitzgerald, JD, Khanna PP, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia gout. Arthritis Care Res. October 2012; 64(10): 1431-1446.
3. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care & Research. June 2020; 0 (0): 1-17.
4. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 20, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2507	Injection, pegloticase, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: No significant changes. Policies combined for Medicaid and Commercial lines of business. References reviewed and updated.	11.22.17	02.18
1Q 2019 annual review: removed the requirement for G6PD deficiency testing to align with the previously approved Corporate approach for G6PD deficiency testing; references reviewed and updated.	11.06.18	02.19
1Q 2020 annual review: no significant changes; added HIM line of business; references reviewed and updated.	10.28.19	02.20
1Q 2021 annual review: no significant changes; added requirement in continued therapy that member is not concurrently taking other oral urate-lowering therapy to Section I for initial approval; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.16.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated	11.20.21	02.22

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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