RXADVANCE
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Clinical Policy Title:	pegloticase
Policy Number:	RxA.182
Drug(s) Applied:	Krystexxa®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pegloticase (Krystexxa)	Chronic gout	8 mg IV every 2 weeks	8 mg/2 weeks

Dosage Forms

- Vial: 8 mg of uricase protein/1 mL

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of chronic gout;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Positive for symptomatic gout with one or more of the following:
   a. At least 2 gout flares in the previous 12 months;
   b. At least 1 gout tophus;
   c. Chronic gouty arthritis;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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5. Failure to normalize uric acid to < 6 mg/dL with at least 3 months each of allopurinol and Uloric®, at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of one uricosuric agent (e.g., probenecid or Zurampic®), at maximally indicated doses, in combination with allopurinol or Uloric® unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 8 mg (uricase protein) every two weeks;
8. Has tested negative for glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by a decrease in plasma uric acid levels;
3. Member is not concurrently taking any 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
Commercial: 6 months
Medicaid: 12 months

III. Appendices

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	Maximum Dose
allopurinol (Zyloprim®)	400-600 mg PO once daily	600 mg/day
Uloric® (febuxostat)	40 mg PO once daily	80 mg/day
probenecid	500 mg PO twice daily	2 gm/day
Zurampic® (lesinurad)	200 mg PO once daily	200 mg/day

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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
  - Should pre-medicate with antihistamines and corticosteroids
  - G6PD deficiency-associated hemolysis and methemoglobinemia

APPENDIX D: General Information

- Not Applicable

References

1. Krystexxa Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; January 2020. Available at: https://hznp.azureedge.net/public/KRYSTEXXA_Prescribing_Information.pdf. Accessed June 19, 2020.
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. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 19, 2020.
4. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care Res (Hoboken)*. June 2020;72(6):744-760. doi:10.1002/acr.24180.
5. Krystexxa. Lexi-Drugs. Hudson, OH: Lexicomp, 2020. http://online.lexi.com/. Updated March 2, 2020. Accessed July 9, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Background was updated to include limitations of use. 3. Initial Approval criteria I.A.2 was added to specify prescriber type. 4. Initial Approval criteria I.A.4a was updated to 2 flares within 12 months. 5. Initial Approval criteria I.A.6 updated to remove losartan and add Zurampic as uricosuric agent. 6. Initial Approval criteria I.A.8	07/09/2020	09/14/2020

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was added to include negative G6PD deficiency result due to contraindication. 7. Initial and Continued Therapy approval durations updated to exactly 6 months. 8. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 9. Appendix B updated to remove losartan and add Zurampic as therapeutic alternative. 10. Appendix C updated to add requirement of pre-medication with antihistamines and corticosteroids. 11. References were updated.		

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