

Policy Name:	Krystexxa (pegloticase)	Policy#:	2418P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Krystexxa (pegloticase).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Krystexxa (pegloticase) under the specialty medical benefit if the following criteria are met.

Criteria

1. Criteria for coverage of Krystexxa

- 1.1 Diagnosis of symptomatic chronic gout
- 1.2 Documentation that the member is not at high risk for a G6PD deficiency (a genetic disorder that causes red blood cells to break down prematurely)
 - If the member is at high risk for G6PD deficiency, submission of lab results which indicate no G6PD deficiency
- 1.3 Documented 3-month trial and failure, intolerance, or contraindication a xanthine oxidase inhibitor:
 - Allopurinol or febuxostat
- 1.4 Documentation to support Krystexxa will be taken with methotrexate unless contraindicated
 - This requirement can be bypassed if patient is already stabilized on another immunosuppressant due to this increased risk of significant immunosuppression

2. Approval Time

- 2.1 Initial Approval: 12 months
- 2.2 Reapproval: 12 months with documentation that the member has not had 2 consecutive uric acid levels above 6mg/dL

CPT Codes

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HCPCS Codes

J2507	Injection, pegloticase, 1mg
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References

1. Krystexxa (pegloticase) [prescribing information]. Deerfield, IL: Horizon Therapeutics USA Inc; July 2022.
2. Hamburger M, Baraf HS, Adamson TC, et al. 2011 Recommendations for the diagnosis and management of gout and hyperuricemia. *Postgrad Med.* 2011;123(6 Suppl 1):3–36.
3. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. *Arthritis Care Res (Hoboken).* 2020;72(6):744-760.
4. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the

management of gout. Ann Rheum Dis. 2017;76(1):29-42.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.