

Title: *pegloticase (Krystexxa)*

Origination: 05/25/11	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Pegloticase is a pegylated, recombinant, mammalian urate oxidase enzyme not found naturally in humans.
- Pegloticase has a novel mechanism of action; it lowers uric acid concentrations by converting uric acid into allantoin (a benign metabolite) that is easily excreted in the urine.
- In September 2010, pegloticase (Krystexxa) was FDA approved for the treatment of chronic gout in adult Members refractory to conventional therapy.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Member has glucose-6-phosphate deficiency (G6PD).
- Member is less than 18 years of age, as safety and efficacy has not been established in children or adolescents.

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Procedure:

- 1.0 Request for *initiation* with Krystexxa for **treatment-failure symptomatic gout** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Provider is medical rheumatologist or a nephrologist; **AND**
 - 1.2 Member, if of African or Mediterranean ancestry, has had as negative screening for G6PD; **AND**
 - 1.3 Member has a baseline serum uric acid (SUA) of at least 8 mg/dL; **AND**
 - 1.4 Member has diagnosis of symptomatic gout with at least three (3) gout flares in the previous 18 months or at least one (1) gout tophus or gouty arthritis; **AND**
 - 1.5 Member shows inadequate response (failure to normalize serum uric acid to less than 6mg/dl) or has documented contraindication to a three (3) to six (6) month minimum trial of both of the following medications:
 - 1.5.1 Allopurinol;
 - 1.5.2 Febuxostat;
 - 1.6 If all criteria are met, initial therapy with Krystexxa may be approved at 8mg intravenously every two (2) weeks for three (3) months or a maximum of six (6) infusions.
- 2.0 Request for *continuation of therapy* beyond the initial authorization period for **treatment-failure symptomatic gout** requires documentation from the member's medical records maintained by the requesting independent practitioner verifying a reduction in the Member's signs and symptoms of gout (serum uric acid level less than 6mg/dl):
 - 2.1 If criteria are met, continuation of Krystexxa 8mg IV every two (2) weeks may be approved for three (3) months or a maximum of six (6) infusions.

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References:

1. Sundy JS, Becker MA, Baraf HS, et al. Reduction of plasma urate levels following treatment with multiple doses of pegloticase (polyethylene glycol-conjugated uricase) in patients with treatment-failure gout: results of a phase II randomized study. *Arthritis Rheum* 2008;58:2882-91.
2. Clinical Pharmacology Online, Elsevier, Krystexxa package insert. East Brunswick, NJ: Savient Pharmaceuticals, Inc., 2010 Sept.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.