Clinical Criteria

Subject:	Krystexxa (pegloticase)		
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Status:	Revised	**Last Review Date**:	~~05/17/2019~~05/15/2020

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Overview

This document addresses the use of Krystexxa (pegloticase). Krystexxa is a recombinant uricase enzyme that achieves its therapeutic effect by catalyzing the oxidation of uric acid to allantoin, thereby lowering serum uric acid.

Krystexxa is approved by the Food and Drug Administration for the treatment of chronic gout in adults that are refractory to conventional therapy. In the clinical trials that supported the approval of Krystexxa, chronic refractory gout was defined as three or more self-reported gout flares during the previous 18 months, one or more tophi or gouty arthropathy defined clinically or radiographically as joint damage due to gout.

The 2012 American College of Rheumatology (ACR) guidelines for the management of gout recommend xanthine oxidase inhibitor therapy with either allopurinol or febuxostat as first-line urate lowering therapy (ULT). The serum urate level should be lowered sufficiently to improve signs and symptoms of gout with a target of <6 mg/dL at a minimum. ACR guidance recommends the addition of a uricosuric agent, for example probenecid, as an alternate effective therapeutic option. ACR guidance states Krystexxa is appropriate for individuals with severe gout disease burden and refractoriness to or intolerance of conventional ULT. Krystexxa is not recommended as first-line ULT or for the treatment of asymptomatic hyperuricemia.

Krystexxa has a black box warning for anaphylaxis and infusion reactions, glucose-6-phosphate dehydrogenase (G6PD) deficiency associated hemolysis and methemoglobinemia. Krystexxa should be administered in a healthcare setting and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Individuals should be pre-medicated with antihistamines and corticosteroids for each infusion and closely monitored for symptoms of anaphylaxis. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL. Individuals at risk for G6PD deficiency (i.e. African, Mediterranean, and Southern Asian ancestry) should be screened prior to starting Krystexxa. Hemolysis and methemoglobinemia have been reported with Krystexxa in individuals with G6PD deficiency. Do not administer Krystexxa to individuals with G6PD deficiency.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Krystexxa (pegloticase)

Initial ~~R~~requests for Krystexxa (pegloticase) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has 1 or more of the following (Sundy 2011):
   A. Three~~3~~ or more gout flares in the previous 18 months; **OR**
   B. One~~1~~ or more tophus present; **OR**
   C. History of chronic gouty arthropathy, defined clinically or radiographically as joint damage due to gout.

AND

III. Individual has a confirmed baseline serum uric acid of 6 mg/dL or greater prior to initiating Krystexxa (pegloticase) (Khanna 2012); **AND**

IV. Individual has failed to respond to, is intolerant of, or has a medical contraindication to 1 or more of the following conventional therapies (Khanna 2012):
   A. A xanthine oxidase inhibitor (allopurinol or febuxostat); **OR**
   B. Combination therapy of 1 xanthine oxidase inhibitor given with a uricosuric agent (~~i.e.~~ for example, probenecid).

Continuation requests for Krystexxa (pegloticase) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement in clinical signs and symptoms of disease (including but not limited to reduction in serum uric acid level, gout flare reduction, tophus resolution, reduction in joint pain) (Sundy 2011).

Krystexxa (pegloticase) may not be approved for the following:

I. All other indications not included above; **OR**

~~I.~~II. Individual has asymptomatic hyperuricemia; **OR**

~~II.~~III. Individual has a known glucose-6-phosphate dehydrogenase (G6PD) deficiency.

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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J2507	Injection, pegloticase, 1mg [Krystexxa]

ICD-10 Diagnosis

M1A.00X0-M1A.9XX1	Chronic gout
M10.00-M10.9	Gout

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Document History

Revised: 5/15/2020
Document History:

- 5/15/2020 – Annual Review: Addition of continuation criteria. Wording and formatting changes. Coding Reviewed: No changes.
- 5/17/2019 – Annual Review: Wording and formatting changes. Coding reviewed: no changes.
- 11/16/2018 – Select Review: Initial P&T Review of Krystexxa (pegloticase). Update criteria with off-label references. Minor wording and formatting changes. HCPCs and ICD-10 Review: No changes.

References

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3. 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. *Arthritis Care Res*. 2012 Oct;64(10):1431-46.
4. Khanna D, Khanna PP, Fitzgerald JD, et.al. 2012 American College of Rheumatology guidelines for management of gout. Part 2: Therapy and antiinflammatory prophylaxis of acute gouty arthritis. *Arthritis Care Res*. 2012 Oct;64(10):1447-61.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. JAMA 2011; 306:711–720.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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