

EFFECTIVE DATE: 02/15/2011

POLICY LAST UPDATED: 07/01/2014

OVERVIEW

This policy documents the coverage criteria for Pegloticase. Pegloticase (Krystexxa™) is a pegylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Pegloticase (Krystexxa™) is medically necessary when the criteria listed below have been met. All other indications would be considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

Blue CHiP for Medicare and Commercial

Krystexxa is medically necessary when the member meets the criteria listed below:

- A.** Patient has a diagnosis of symptomatic chronic gout (e.g., tophi, gouty arthropathy, radiographic changes of gout, multiple joint involvement, associated uric acid nephrolithiasis); **and**
- B.** Patient has a pre-treatment uric acid level of at least 6 mg/dl **and**
- C.** Patient has tried but had a documented inadequate response to at least 3 months of xanthine oxidase (XO) inhibitor therapy (allopurinol or febuxostat) at the maximum medically appropriate dose; **or**
- D.** Patient was not able to complete a 3-month trial of XO inhibitor therapy for one of the following documented clinical reasons:
 - Patient experienced a severe allergic reaction to the XO inhibitor
 - Patient experienced toxicity with the XO inhibitor
 - Patient could not tolerate the XO inhibitor
 - Significant drug interaction with the XO inhibitor
 - Severe renal dysfunction (for allopurinol only)

BACKGROUND

Pegloticase (Krystexxa™) has been indicated for the treatment of chronic gout in adult patients who remain refractory to conventional therapy, Pegloticase (Krystexxa™) is a PEGylated uric acid specific enzyme that reduces serum uric acid levels by catalyzing the oxidation of uric acid to allantoin.

Pegloticase (Krystexxa™) is a pegylated uric acid specific enzyme that consists of recombinant modified mammalian urate oxidase produced by a genetically modified strain of *Escherichia coli* (Krystexxa™ prescribing information, 2010). It is approved for the treatment of chronic gout in adult patients refractory to conventional therapy.

Krystexxa™ is not recommended for the treatment of asymptomatic hyperuricemia.¹

The following requirements should be documented in the medical records:

- Uric acid levels will be monitored prior to each infusion; and
- For continuation of therapy, two consecutive uric acid levels must NOT be above 6 mg/dL; and
- Patients at high risk for glucose 6-phosphate dehydrogenase (G6PD) deficiency (e.g., African or Mediterranean ancestry) must be screened before initiation of therapy and must have negative results; and
- Krystexxa will be administered in a healthcare setting with access to management of severe anaphylaxis and infusion reactions; and
- Patient will be premedicated with antihistamines and corticosteroids prior to each infusion.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable infusion coverage/benefits.

Specialty Pharmacy

For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

CODING

Blue CHiP for Medicare and Commercial

The following HCPC code is medically necessary when medical criteria are met:

J2507

RELATED POLICIES

None

PUBLISHED

Provider Update Sep 2014

Provider Update May 2013

Provider Update Apr 2012

REFERENCES

Conway N, Schwartz S. Diagnosis and management of acute gout. *Medicine and Health/Rhode Island*; 2009; 92(11); 345-358

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Rider TG, Jordan KM. The Modern Management of Gout. *Oxford Journals; Medicine; Rheumatology*; 49(1):5-14. <http://rheumatology.oxfordjournals.org/content/49/1/5.full.pdf+html>.

Smith RG. The Diagnosis and Treatment of Gout. *US Pharmacist*; May 19, 2009; 34(5):40-7. <http://www.uspharmacist.com/content/d/feature/i/734/c/13430>.

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