



**EFFECTIVE DATE:** 02|11|2011  
**POLICY LAST UPDATED:** 10|06|2015

## OVERVIEW

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

## MEDICAL CRITERIA

### BlueCHiP for Medicare and Commercial Products

Pegloticase (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)

## PRIOR AUTHORIZATION

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

## POLICY STATEMENT

### BlueCHiP for Medicare and Commercial Products

Pegloticase is medically necessary when the criteria listed above 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.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or 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.

## BACKGROUND

Pegloticase (Krystexxa™) has been indicated for the treatment of chronic gout in adult patients' 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 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.<sup>1</sup>

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.

#### **CODING**

##### **BlueCHiP for Medicare and Commercial Products**

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

**J2507**

#### **RELATED POLICIES**

None

#### **PUBLISHED**

Provider Update, December 2015

Provider Update, September 2014

Provider Update, May 2013

Provider Update, April 2012

#### **REFERENCES**

1. Conway N, Schwartz S. Diagnosis and management of acute gout. *Medicine and Health/Rhode Island*; 2009;92(11):f345-358.
2. Pillinger MH, and Keenan RT. Update on the Management of Hyperuricemia and Gout. *Bulletin of the NYU Hospital for Joint Diseases*; 2008;66(3):231-9.
3. 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>.

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