

**EFFECTIVE DATE:** 06|01|2018

**POLICY LAST UPDATED:** 05|15|2018

## OVERVIEW

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

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

## MEDICAL CRITERIA

### BlueCHiP for Medicare

**Krystexxa (pegloticase)** will be approved when ALL of the following are met:

1. ONE of the following:

A. There is documentation that the patient is currently being treated with the requested agent for an FDA approved indication

**OR**

B. The prescriber states the patient is using the requested agent for an FDA approved indication AND is at risk if therapy is changed

**OR**

C. ALL of the following:

i. The patient has a baseline serum uric acid level of at least 8 mg/dL

**AND**

ii. ONE of the following:

1. The patient has symptomatic gout with at least 3 gout flares in the previous 18 months

**OR**

2. The patient has at least 1 gout tophus or gouty arthritis

**AND**

iii. ONE of the following:

1. The patient is currently (within the last 30 days) receiving prophylaxis for gout flares with NSAIDS or colchicine or both

**OR**

2. The patient had a documented intolerance, FDA labeled contraindication or hypersensitivity to both NSAIDS and colchicine

**AND**

iv. ONE of the following:

1. The patient has had an insufficient response (defined as uric acid levels > 6 mg/dL) to at least 3 months of therapy with both allopurinol and febuxostat at maximum tolerated doses

**OR**

2. The patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to both allopurinol and febuxostat

**AND**

2. The patient does not have any FDA labeled contraindications to therapy with the requested agent  
**AND**
3. The dose is within the FDA labeled dose

**Length of Approval:** 6 months

### **Renewal Evaluation**

Krystexxa (pegloticase) will be renewed when ALL the following are met:

1. The patient has been previously approved for therapy through the BCBSRI Medical Drug Review process  
**AND**
2. The patient does not have 2 consecutive uric acid levels > 6 mg/dL while on therapy  
**AND**
3. The patient does not have any FDA labeled contraindications to therapy with the requested agent  
**AND**
4. The dose is within the FDA labeled dose

**Length of Approval:** 12 months

### **PRIOR AUTHORIZATION**

Prior authorization is required for BlueCHIP for Medicare

### **POLICY STATEMENT**

#### **BlueCHIP for Medicare**

Krystexxa (Pegloticase) is medically necessary when the criteria listed above have been met.

### **COVERAGE**

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage for applicable physician administered drug benefits/coverage.

### **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.

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

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

**J2507** Injection, Pegloticase, 1 mg

### RELATED POLICIES

Prior Authorization of Drugs

### PUBLISHED

Provider Update, June 2018

Provider Update, January 2018

Provider Update, December 2016

Provider Update, December 2015

Provider Update, September 2014

Provider Update, May 2013

Provider Update, April 2012

### REFERENCES

1. Krystexxa prescribing information. Crealta. May 2016.
2. Khanna, D., et al. 2012 American College of Rheumatology Guideline Management of Gout part 1. *Arthritis Care & Research*: Vol 64, No 10, October 2012, pp 1431-1446. .
3. Rothschild BM. Gout and Psuedogout. Medscape.
4. Sivera F, Andres M, Carmona L et al. Recommendations for the Diagnosis and Management of Gout. *Ann Rheum Dis* 2014; 73(2):328-335.
5. Qaseem Amir, et al. Management of Acute and Recurrent Gout: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. Doi: 10.7326/M16-0570. November 2016.

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