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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