Medical Coverage Policy

Pegloticase

☐ Device/Equipment ☒ Drug ☐ Medical ☐ Surgery ☐ Test ☐ Other

Effective Date:	2/15/2011	Policy Last Updated:	3/5/2013

☒ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☐ **Prospective review is not required.**

Description:
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 requirments 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.

Medical Criteria:
Krystexxa is medically necessary when the member meets two of the three criteria listed below:

I. 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

II. 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

III. Patient was not able to complete a 3-month trial of XO inhibitor therapy for one of the following documented clinical reason

- 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)

Policy:
Pegloticase (Krystexxa™) is medically necessary when the criteria listed above has been met.

Prior authorization is required for BlueCHiP for Medicare and recommended for all other lines of business.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet 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:
J2507

Also known as:
Krystexxa™

Related topics:
Not applicable

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

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.

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.

History:
3/5/13 Annual review
2/7/12 Annual review
2/15/11 New policy approved

agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.