EFFECTIVE DATE: 02|11|2011
POLICY LAST UPDATED: 11|21|2017

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

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

The requested agent will also be approved when the following are met:

1. The patient does not have any FDA labeled contraindications to therapy with the requested agent
   AND
2. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).
   AND
3. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

   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

The requested agent will also be approved when 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 any FDA labeled contraindications to therapy with the requested agent
   AND
3. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).
   AND
4. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

Length of Approval: 12 months

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

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Pegloticase (Krystexxa) is medically necessary when the criteria listed above have been met.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable physician administered drug benefits/coverage.

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.

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 Injection, Pegloticase, 1 mg

RELATED POLICIES
None

PUBLISHED
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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