Effective Date: 05/03/2018

Krystexxa®(pegloticase)

FDA approval: September 14, 2010
HCPCS: J2507
Benefit: Medical

Policy/Criteria:

Note: Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the below criteria are met:
   a. ≥ 18 years of age
   b. Three gouty flares or more in previous 18 months
   c. Presence of one or more tophi
   d. Chronic gouty arthritis
   e. Serum uric acid greater than 8 mg/dL
   f. Treatment with maximally titrated doses of allopurinol (800 mg) and febuxostat (80 mg) is contraindicated, not tolerated, or have been ineffective
   g. Cannot have a known G6PD deficiency

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: One 8 mg infusion every two weeks
   b. Initial Authorization Period: 1 year
   c. Renewal Criteria:
      1. Authorization will be reviewed annually thereafter to assess treatment response

C. Krystexxa® is considered investigational when used for all other conditions, including but not limited to:
   a. Hyperuricemia not associated with gout
   b. Asymptomatic hyperuricemia

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia

Therapeutic considerations:

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.
A. FDA approved indication / Diagnosis
   Indication: the treatment of chronic gout in adult patients refractory to conventional therapy
   Limitation: Not recommended for treatment of asymptomatic hyperuricemia

   *Please refer to most recent prescribing information.

B. Background Information
   a. Krystexxa® (pegloticase) is an intravenously administered PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Refractory gout occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for those whom conventional treatment is contraindicated.
   b. Two xanthine oxidase inhibitors that are successfully utilized in lowering serum uric acid levels include allopurinol as well as febuxostat. The initial daily dose of allopurinol is 300 mg/d orally for most patients who have normal kidney function; the dose of allopurinol should be increased in 100-mg increments to achieve the desired serum uric acid level of ≤5.0 mg/dL. Successful treatment usually requires a dose of 300–400 mg of allopurinol daily titrated to a maximum daily dose is 800 mg. Nevertheless the vast majority of allopurinol prescriptions are for doses < or = 300 mg/d, which often fails to adequately treat hyperuricemia in gout.
   c. Febuxostat can be used up to 80 mg daily. In an open-label extension study, it was discovered that patients continuing to receive a fixed dose of either 80 mg or 120 mg of febuxostat, resulted in near elimination of gout flares and improved tophus status over the course of 40 months.

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C. Efficacy

   *Please refer to most recent prescribing information.

D. Medication Safety Considerations

   Boxed Warning: Yes

   *Please refer to most recent prescribing information.

E. Dosing and administration
   a. Dosing:
      i. 8mg every 2 weeks

   *Please refer to most recent prescribing information.

F. How supplied
   a. Single Dose Vial
      i. 8mg/1ml

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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm)