Krystexxa (pegloticase)

**Line(s) of Business:**
- HMO; PPO; QUEST Integration
- Akamai Advantage

**Effective Date:** 10/01/2015

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no contraindications or exclusions to the prescribed therapy.

**FDA-Approved Indication**
- Chronic gout
  - Krystexxa is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Gout refractory to conventional therapy 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 whom these drugs are contraindicated.

**Limitations of Use:**
Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

**B. CRITERIA FOR APPROVAL**

1. **Chronic Gout**

Authorization of 6 months may be granted to members who meet ALL of the following criteria:

a. Member has a diagnosis of symptomatic chronic gout (e.g., evidence of tophi, gouty arthropathy, radiographic changes of gout, multiple joint involvement, or associated uric acid nephrolithiasis).

b. Krystexxa will NOT be used concomitantly with oral urate-lowering agents.

c. Member has had an inadequate response to at least a 3 month trial of allopurinol at the maximum medically appropriate dose OR member has any of the following clinical reasons for not completing a 3 month trial of allopurinol at the maximum medically appropriate dose:
   i. Member experienced a severe allergic reaction to allopurinol.
   ii. Member experienced toxicity with allopurinol.
   iii. Member could not tolerate allopurinol.
   iv. There is a significant drug interaction with allopurinol.
   v. Member has severe renal dysfunction.
d. Member has had an inadequate response to at least a 3 month trial of febuxostat (Uloric) at the maximum medically appropriate dose OR member has any of the following clinical reasons for not completing a 3 month trial of febuxostat (Uloric) at the maximum medically appropriate dose:
   i. Member experienced a severe allergic reaction to febuxostat.
   ii. Member experienced toxicity with febuxostat.
   iii. Member could not tolerate febuxostat.
   iv. There is a significant drug interaction with febuxostat.

C. CONTINUATION OF THERAPY
   a. Reauthorization of 6 months may be granted to members requesting authorization for continuation of therapy previously authorized by HMSA when ALL of the following criteria are met:
      i. Member has a diagnosis of symptomatic chronic gout (e.g., evidence of tophi, gouty arthropathy, radiographic changes of gout, multiple joint involvement, or associated uric acid nephrolithiasis).
      ii. Krystexxa will NOT be used concomitantly with oral urate-lowering agents.
      iii. Member has NOT had two consecutive uric acid levels above 6 mg/dL.

   b. Authorization of up to 6 months may be granted to members requesting authorization for continuation of therapy not previously authorized by HMSA when the following criteria are met:
      i. Member meets all initial criteria (refer to section B.1.).
      ii. Member has NOT had two consecutive uric acid levels above 6 mg/dL (applicable if member received at least 6 months of therapy).

D. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

E. IMPORTANT REMINDER
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

   This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
F. REFERENCES