Krystexxa (pegloticase)

Line(s) of Business: HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 05/01/2018

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. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Documentation supporting an inadequate response to allopurinol, febuxostat (Uloric), and probenecid (or clinical reason that a trial could not be completed)
- Dose and length of therapy with allopurinol and febuxostat (Uloric) and probenecid

C. CRITERIA FOR APPROVAL
1. Chronic Gout
Authorization of 6 months may be granted for members with a diagnosis of chronic gout when ALL of the following criteria are met:
A. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies
B. Member has had an inadequate response to or a clinical reason for not completing at least a three-month trial (see Appendix) with ALL of the following medications at the medically appropriate maximum doses:
   1. Allopurinol
   2. Febuxostat
   3. Probenecid (alone or in combination with allopurinol or febuxostat)
D. APPENDIX: Clinical reasons for not completing a three-month trial with allopurinol, febuxostat, and probenecid (examples):
   A. Member experienced a severe allergic reaction to the medication
   B. Member experienced toxicity with the medication
   C. Member could not tolerate the medication
   D. Member’s current medication regimen has a significant drug interaction
   E. Member has severe renal dysfunction (allopurinol)
   F. Member has known blood dyscrasias or uric acid kidney stones (probenecid)
   G. Member has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)

E. CONTINUATION OF THERAPY
   1. No previous authorization/precertification
      Authorization of up to 6 months may be granted to members and new members requesting authorization for continuation of therapy not previously authorized by HMSA when the following criteria are met:
      a. Member meets all initial criteria in Section C.
   2. Reauthorization
      Reauthorization of 6 months may be granted to members requesting authorization for continuation of therapy if Krystexxa was previously authorized by HMSA/CVS and the following criteria are met:
      a. Member has documented clinical benefit from therapy and;
      b. Member has documented decrease in uric acid levels.

F. ADMINISTRATIVE GUIDELINES
   Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

G. IMPORTANT REMINDER
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate 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.

H. REFERENCES


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**Document History**

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