Krystexxa (pegloticase)

Line(s) of Business:  Original Effective Date:
HMO; PPO; QUEST Integration  10/01/2015
Medicare Advantage  Current Effective Date:

04/01/2019

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
Krystexxa is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:

- Initial therapy
  - 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
- Continuation of therapy
  - Documentation supporting a positive clinical response to therapy with Krystexxa (e.g., chart notes, medical records)
  - Current uric acid levels

C. CRITERIA FOR APPROVAL
Chronic Gout
Authorization of 12 months may be granted for members with a diagnosis of chronic gout when ALL of the following criteria are met:

1. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies
2. 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:
   a. Allopurinol
   b. Febuxostat
   c. Probenecid (alone or in combination with allopurinol or febuxostat)

D. CONTINUATION OF THERAPY
Authorization of 12 months may be granted for all members (including new members) with a diagnosis of chronic gout that meet ALL initial authorization criteria and have NOT had two consecutive uric acid levels above 6 mg/dL since starting treatment with Krystexxa.

E. APPENDIX: Clinical reasons for not completing a three-month trial with allopurinol, febuxostat, and probenecid (examples):
1. Member experienced a severe allergic reaction to the medication
2. Member experienced toxicity with the medication
3. Member could not tolerate the medication
4. Member’s current medication regimen has a significant drug interaction
5. Member has severe renal dysfunction (allopurinol)
6. Member has known blood dyscrasias or uric acid kidney stones (probenecid)
7. Member has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)

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 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/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA 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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