

SPECIALTY GUIDELINE MANAGEMENT

KRYSTEXXA (pegloticase)

POLICY

I. 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 exclusions to the prescribed therapy.

FDA-Approved Indication

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL 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:

- 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)

III. 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.

IV. 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)

V. REFERENCES

- 1. Krystexxa [package insert]. Bridgewater, NJ: Savient Pharmaceuticals, Inc.; September 2016.

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