

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 6 months may be granted for members with a diagnosis of chronic gout, and dose is within FDA guidelines 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 6 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.

2. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, Michigan. Available at <http://www.micromedexsolutions.com>. Accessed February 22, 2018.
3. Khanna D, Fitzgerald JD, Khanna PP, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. *Arthritis Care Res*. 2012;64(10):1431-1446.
4. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis*. 2017;76:29-42.
5. Khanna D, Khanna PP, Fitzgerald JD, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 2: therapy and antiinflammatory prophylaxis of acute gouty arthritis. *Arthritis Care Res*. 2012;64(10):1447-1461.
6. Hui M, Carr A, Cameron S, et al. The British Society for Rheumatology Guideline for the Management of Gout. *Rheumatology*. 2017;56(7):e1–e20. Available at <https://doi.org/10.1093/rheumatology/kex156>.
7. Sivera F, Andres M, Carmona L, et al. Multinational evidence-based recommendations for the diagnosis and management of gout: integrating systemic literature review and expert opinion of a broad panel of rheumatologists in the 3e initiative. *Ann Rheum Dis*. 2014;73(2):328-335.
8. Probenecid [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; March 2006.