Reference number
1803-A

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.
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.