

Policy Title:	Krystexxa (pegloticase) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	9/18/2019, 12/20/2019		
Revision Date:	9/18/2019		

Purpose: To support safe, effective and appropriate use of Krystexxa (pegloticase).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Krystexxa (pegloticase) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Krystexxa (pegloticase) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Authorization 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:
 - Krystexxa will NOT be used concomitantly with oral urate-lowering therapies; AND
 - 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:
 - Allopurinol
 - Febuxostat
 - Probenecid (alone or in combination with allopurinol or febuxostat)

Continuation of Therapy Criteria:

- Authorization 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

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 1 mg)
All indications	8 mg given as an intravenous infusion every two weeks	16 billable units every 28 days

Appendix:

Clinical reasons for not completing a three-month trial with allopurinol, febuxostat, and probenecid (examples):

- Member experienced a severe allergic reaction to the medication
- Member experienced toxicity with the medication
- Member could not tolerate the medication
- Member's current medication regimen has a significant drug interaction
- Member has severe renal dysfunction (allopurinol)
- Member has known blood dyscrasias or uric acid kidney stones (probenecid)
- Member has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from

tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J2507	Injection, pegloticase, 1 mg

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.