Policy Title:	Krystexxa (pegloticase) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	9/18/2019, 12/20/2019, 1/22/20, 11/2/2020		
Revision Date:	9/18/2019, 1/22/20, 11/2/2020		

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

Scope: Medicaid, Commercial, 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*)
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

* MMP members ONLY are not required to try this agent

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):

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)

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.