Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Krystexxa (pegloticase)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Krystexxa (pegloticase)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Krystexxa (pegloticase) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has 1 or more of the following (Sundy 2011):
    A. Three or more gout flares in the previous 18 months; **OR**
    B. One or more tophus present; **OR**
    C. History of chronic gouty arthropathy, defined clinically or radiographically as joint damage due to gout;

AND

III. Individual has a baseline serum uric acid of 6 mg/dL or greater prior to initiating Krystexxa (pegloticase) (Khanna 2012);

AND

IV. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more of the following conventional therapies (Khanna 2012):
    A. A xanthine oxidase inhibitor (allopurinol or febuxostat); **OR**
    B. Combination therapy of 1 xanthine oxidase inhibitor given with a uricosuric agent (for example, probenecid).

Continuation requests for Krystexxa (pegloticase) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement in clinical signs and symptoms of disease (including but not limited to reduction in serum uric acid level, gout flare reduction, tophus resolution, reduction in joint pain) (Sundy 2011).

Krystexxa (pegloticase) may **not** be approved for the following:

I. All other indications not included above; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

II. Individual has asymptomatic hyperuricemia; **OR**
III. Individual has a known glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 29, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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 Oct;64(10):1431-46.
4. 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 Oct;64(10):1447-61.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. JAMA 2011; 306:711–720.