Mass General Brigham
Health Plan

Krystexxa (pegloticase)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

FDA-Approved Indication

Krystexxa (pegloticase) is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Requested medication will NOT be used concomitantly with oral urate-lowering therapies
3. Member meets ONE of the following:
    a. ≥ 2 gout flares in the past 12 months
    b. Presence of ≥ 1 tophus
    c. Gouty arthritis
4. Member has had an inadequate response to or a clinical reason for not completing at least a three-month trial (see Appendix) with the following medications at the medically appropriate maximum doses:
    a. Allopurinol or febuxostat
    b. Probenecid (alone or in combination with allopurinol or febuxostat)

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. Member is 18 years of age or older.
2. The requested medication will NOT be used concomitantly with oral urate-lowering therapies.

3. Submission of documentation demonstrating that member is experiencing benefit from therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares).

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

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

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)
H. Member has end stage renal impairment (febuxostat)
I. Member has a history of CVD or a new CV event (febuxostat)

References

1. Febuxostat [prescribing information]. Eatontown, NJ: Hikma Pharmaceuticals USA Inc.; July 2019.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in *Arthritis Care Res (Hoboken)*. 2020 Aug;72(8):1187]. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
3. 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.
4. 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.
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. Krystexxa (pegloticase) [prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; July 2022.
7. Probenecid [prescribing information]. Parsippany, NJ: Actavis Pharma, Inc.; December 2016.
8. 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.
9. Sivera F, Andres M, Carmona L, et al. Multinational evidence-based recommendations for the diagnosis and management of gout: integrating systematic literature review and expert opinion of a broad panel of rheumatologists in the 3e initiative. *Ann Rheum Dis.* 2014;73(2):328-335.

Review History

12/13/2023 - Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024
12/11/2024 – Reviewed and updated at December P&T. Refined diagnostic language in initial criteria. Removed methotrexate co-administration requirement. Removed reauthorization requirement that member has not had two consecutive uric acid levels above 6 mg/dL since starting Krystexxa. Effective 3/1/2025.