Mass General Brigham
Health Plan

Krystexxa (pegloticase)
Effective 01/01/2024

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 is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Limitations of Use

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Guidelines

Authorization may be granted for members new to the plan 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 the following criteria is 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. The member has at least 2 flares per year that were inadequately controlled by colchicine or NSAIDs or at least 1 gout tophus or 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 A) with the following medications at the medically appropriate maximum doses:
    a. Allopurinol or febuxostat
    b. Probenecid (alone or in combination with allopurinol or febuxostat)
5. The member meets one of the following criteria:

a. The requested medication will be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation, or
b. The member has a contraindication to or clinical reason to avoid oral methotrexate therapy (see Appendix B).

Continuation of Therapy

Reauthorization may be granted for members with a diagnosis of chronic gout 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. The member meets one of the following:
    a. The requested medication will be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation, or
    b. The member has a contraindication to or clinical reason to avoid oral methotrexate therapy (see Appendix B).
4. Member has NOT had two consecutive uric acid levels above 6 mg/dL since starting treatment with Krystexxa.
5. Submission of documentation supporting 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

Appendix A: 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)

Appendix B: Contraindications/clinical reasons to avoid oral methotrexate therapy (examples, not all inclusive):

A. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
B. Breastfeeding
C. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
D. Elevated liver transaminases

E. History of intolerance or adverse event
F. Hypersensitivity
G. Interstitial pneumonitis or clinically significant pulmonary fibrosis
H. Myelodysplasia
I. Pregnancy or currently planning pregnancy
J. Renal impairment
K. Significant drug interaction

References

1. Krystexxa [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; July 2022.
2. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at http://www.micromedexsolutions.com. Accessed November 4, 2022.
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.
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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 systematic 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]. Parsippany, NJ: Actavis Pharma, Inc.; December 2016.
9. Febuxostat [package insert]. Eatontown, NJ: Hikma Pharmaceuticals USA Inc.; July 2019.
10. 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.
11. Methotrexate [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; June 2020.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024