CVS Caremark®

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| Reference number(s) |
| 1803-A |

# Specialty Guideline Management Krystexxa

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Krystexxa | pegloticase |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications1

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.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review for continuation of therapy requests: documentation (e.g., chart notes, lab test results) of a response to therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares).

## Coverage Criteria

### Chronic Gout1-10

Authorization of 12 months may be granted for members with a diagnosis of chronic gout when ALL of the following criteria are met:

* Member is 18 years of age or older.
* The requested medication will NOT be used concomitantly with oral urate-lowering therapies.
* 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.
* 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:
  + Allopurinol or febuxostat
  + Probenecid (alone or in combination with allopurinol or febuxostat)
* The member meets one of the following criteria:
  + The requested medication will be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation, or
  + The member has a contraindication to or clinical reason to avoid oral methotrexate therapy (see Appendix B).

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of chronic gout when ALL of the following criteria are met:

* Member is 18 years of age or older.
* The requested medication will NOT be used concomitantly with oral urate-lowering therapies.
* The member meets one of the following:
  + The requested medication will be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation, or
  + The member has a contraindication to or clinical reason to avoid oral methotrexate therapy (see Appendix B).
* Member has NOT had two consecutive uric acid levels above 6 mg/dL since starting treatment with the requested medication.
* Member is experiencing benefit from therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares).

## Appendix

### Appendix A: Clinical Reasons for not Completing a Three-Month Trial with Allopurinol, Febuxostat, and Probenecid (examples, not all inclusive)

* 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)
* Member has end stage renal impairment (febuxostat)
* 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)11

* Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
* Breastfeeding
* Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
* Elevated liver transaminases
* History of intolerance or adverse event
* Hypersensitivity
* Interstitial pneumonitis or clinically significant pulmonary fibrosis
* Myelodysplasia
* Pregnancy or currently planning pregnancy
* Renal impairment
* Significant drug interaction

## References

1. Krystexxa [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; November 2022.
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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 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]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2023.
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.; August 2021.