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 Indications[1]

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).

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Coverage Criteria

Chronic Gout[1-10]

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

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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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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.