

Krystexxa® (pegloticase)

When requesting Krystexxa® (pegloticase), the individual requiring treatment must be diagnosed with an FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

Krystexxa® (pegloticase) is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Approved Off-label Compendial Uses

- Nephrolithiasis
- Gouty nephropathy

Coverage Guidelines

For all indications, an individual meets all of the following criteria:

- Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist
- For re-authorization, an individual is responding to therapy with evidence of serum uric acid level less than 6 mg/dL AND continuing Krystexxa to maintain response/remission

For chronic gout (initial authorization):

- An individual has current symptoms of gout (e.g., gout flares, gout tophus, gouty arthritis) **AND**
- An individual has had an inadequate response (i.e. serum uric acid level greater than 6 mg/dL) following a 3-month trial of at least 2 of the following agents: allopurinol, Uloric (febuxostat), probenecid, fenofibrate, Zurampic, Duzallo, losartan **OR**
- An individual has contraindication or intolerance to a trial of both allopurinol and Uloric (febuxostat)

For nephrolithiasis/gouty nephropathy (initial authorization):

- An individual has had an inadequate response (i.e., serum uric acid level greater than 6 mg/dL) following a 3-month trial of allopurinol or Uloric (febuxostat) **OR**
- An individual has contraindication or intolerance to a trial of both allopurinol and Uloric (febuxostat)

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendation

The recommended dose is 8 mg given as an intravenous infusion every 2 weeks.

References

1. Krystexxa™ injection for intravenous infusion [prescribing information]. East Brunswick, NJ: Savient Pharmaceuticals; July 2018.
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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;64:1431-1446.
4. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis*. 2016 Jul 25. [Epub ahead of print].
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6. Marasini B, Massarotti M. What rheumatologists should know about gout and cardiovascular disease. *J Rheumatol*. 2009;36(4):854-855.
7. Sivera F, Andrés 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. Assadi F. Managing new-onset gout in pediatric renal transplant recipients: when, how, to what extent. *J Nephrol*. 2013;26(4):624-628.
9. Wiederkehr MR, Moe OW. Uric Acid Nephrolithiasis: a systemic metabolic disorder. *Clin Rev Bone Miner Metab*. 2011;9(3-4):207-217.
10. Shen Z, Rowlings C, Kerr B, et al. Pharmacokinetics, pharmacodynamics, and safety of lesinurad, a selective uric acid reabsorption inhibitor, in healthy adult males. *Drug Des Devel Ther*. 2015;9:3423-3434.
11. Gout. Centers for Disease Control and Prevention [Web site]. Last updated April 3, 2018. Available at: <http://www.cdc.gov/arthritis/basics/gout.html>. Accessed on October 10, 2018.