



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 with Krystexxa treatments and is continuing therapy 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, defined as a serum uric acid level that remained greater than 6 mg/dL following a 3-month trial of at least ONE of the following agents: allopurinol, Uloric, or a uricosuric agent (e.g., probenecid, fenofibrate, losartan); **OR**
- An individual has a contraindication or had an intolerance to a trial of allopurinol.

For nephrolithiasis/gouty nephropathy (initial authorization):

- An individual has had an inadequate response, defined as a serum uric acid level that remained greater than 6 mg/dL following a 3-month trial of allopurinol or Uloric; **OR**
- An individual has a contraindication or had an intolerance to a trial of allopurinol.

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; January 2020.
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3. 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.
4. Gout. Centers for Disease Control and Prevention [Web site]. Last reviewed January 28, 2019. Available at: <http://www.cdc.gov/arthritis/basics/gout.html>. Accessed on April 21, 2020.
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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.
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8. Food and Drug Administration. FDA adds Boxed Warning for increased risk of death with gout medicine Uloric (febuxostat). Updated February 21, 2019. Accessed on April 21, 2020. Available at: <https://www.fda.gov/Drugs/DrugSafety/ucm631182.htm>.
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10. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis*. 2017;76(1):29-42.
11. Wiederkehr MR, Moe OW. Uric Acid Nephrolithiasis: a systemic metabolic disorder. *Clin Rev Bone Miner Metab*. 2011;9(3-4):207-217.