

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, patient must meet **all** of the following criteria:

- Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist;
- For re-authorization, patient 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.

Chronic gout (initial authorization):

Patient must meet **all** of the following criteria:

- Has current symptoms of gout (e.g., gout flares, gout tophus, gouty arthritis);
- Meets one of the following:
 - 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);
 - Has a contraindication or had an intolerance to a trial of allopurinol.

Nephrolithiasis/gouty nephropathy (initial authorization):

Patient must meet one of the following criteria:

- 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;
- 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; July 2022.
2. Gout. Centers for Disease Control and Prevention [Web site]. Last reviewed July 27, 2020. Available at: <http://www.cdc.gov/arthritis/basics/gout.html>. Accessed on April 27, 2022.
3. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care Res*. 2020 Jun;72(6):744-760.
4. Wiederkehr MR, Moe OW. Uric Acid Nephrolithiasis: a systemic metabolic disorder. *Clin Rev Bone Miner Metab*. 2011;9(3-4):207-217.

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