Krystexxa® (pegloticase)

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

FDA-approved Indication

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

Coverage Guidelines

Gout, Chronic
The individual must meet all of the following criteria for initial authorization:

- Has at least one tophus OR has a history of 2 previous flares in the past year (prior to the current flare);
- Had an inadequate response, defined as a serum uric acid level that remained greater than 6 mg/dL following a 3-month trial of a xanthine oxidase inhibitor (e.g., allopurinol, febuxostat) unless contraindicated or intolerant to a trial of allopurinol;
- Had an inadequate response, defined as serum uric acid level that remained greater than 6 mg/dL following a 3-month trial of a uricosuric agent (e.g., probenecid, fenofibrate, losartan) unless there is a renal insufficiency (e.g., decreased glomerular filtration rate);
- Krystexxa will be used in combination with one of the following: methotrexate, leflunomide, azathioprine, or mycophenolate mofetil;
- Krystexxa will not be used in combination with an oral urate-lowering drug for the treatment of gout (e.g., allopurinol, febuxostat, or probenecid);
- Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist.

The individual must meet all of the following criteria for re-authorization:

- Is continuing Krystexxa therapy to maintain response/remission;
- Has responded to Krystexxa therapy with evidence of serum uric acid level less than 6 mg/dL;
- Krystexxa is being used in combination with one of the following: methotrexate, leflunomide, azathioprine, or mycophenolate mofetil;
- Krystexxa is not being used in combination with an oral urate-lowering drug for the treatment of gout (e.g., allopurinol, febuxostat, or probenecid);
- Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist.

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™ intravenous infusion [prescribing information]. Lake Forest, IL: Horizon Therapeutics; August 2025.
2. Gout. Centers for Disease Control and Prevention [Web site]. Last reviewed July 27, 2020. Available at: https://www.cdc.gov/arthritis/gout/ Accessed on May 7, 2024.
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. Broadwell A, Albert JA, Padnick-Silver L, LaMoreaux B. Community Practice Experiences with a Variety of Immunomodulatory Agents Co-Administered with Pegloticase for the Treatment of Uncontrolled Gout. *Rheumatol Ther*. 2022;9(6):1549-1558.
5. Khanna PP, Khanna D, Cutter G, et al. Reducing Immunogenicity of Pegloticase With Concomitant Use of Mycophenolate Mofetil in Patients With Refractory Gout: A Phase II, Randomized, Double-Blind, Placebo-Controlled Trial. *Arthritis Rheumatol*. 2021;73(8):1523-1532.
6. Masri KR, Padnick-Silver L, Winterling K, LaMoreaux B. Effect of Leflunomide on Pegloticase Response Rate in Patients with Uncontrolled Gout: A Retrospective Study. *Rheumatol Ther*. 2022;9(2):555-563.