ALASKA MEDICAID
Prior Authorization Criteria

Krystexxa®
(pegloticase)

FDA INDICATIONS AND USAGE[1]

Krystexxa® (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

APPROVAL CRITERIA[1,2,3,4]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a rheumatologist or nephrologist **AND**;
3. Patient has a diagnosis of chronic gout defined by one of the following:
    a. Three or more flares in the past 18 months
    b. Patient has at least 1 gout tophus
    c. Chronic gouty arthritis **AND**;
4. Patient has a baseline serum uric acid level of at least 6 mg/dL **AND**;
5. Patient has been screened for G6PD deficiency **AND**;
6. Patient has a contraindication, intolerance, or treatment failure after 3 months of therapy with both of the following:
    a. Zyloprim (allopurinol)
    b. Uloric (febuxostat) **AND**;
7. Patient is currently (within the last 30 days) receiving prophylaxis for gout flares with NSAIDS, colchicine, or both or has a contraindication for use.

DENIAL CRITERIA [1]

1. Failure to meet approval criteria.

CAUTIONS[1]

- Anaphylaxis can occur with any Krystexxa® infusion. Patients should be pre-medicated and monitored.
- Screen patients at risk for G6PD deficiency.
- Gout flare prophylaxis is recommended for at least the first 6 months of Krystexxa® therapy.
- Congestive heart failure exacerbation may occur. Patients should be monitored accordingly.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months if the prescriber documents positive clinical response to therapy.

QUANTITY LIMIT

- One 8mg IV infusion every two weeks. (16mg per month, 2 vials)
- HCPCS – J2507 (Max 16 billable units)

REFERENCES / FOOTNOTES:

1. Krystexa [prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc. March 2021.
2. Becker MA, Baraf HS, Yood RA, et al. Long-term safety of pegloticase in chronic gout refractory to conventional treatment. Ann Rheum Dis. 2013 Sep 1;72(9):1469-74.
3. . Baraf HS, Becker MA, Gutierrez-Urena SR, et al. Tophus burden reduction with Pegloticase: results from phase 3 randomized trials and open-label extension in patients with chronic gout refractory to conventional therapy. Arthritis Res Ther. 2013 Sep 26;15(5): R137.
4. Smith RG. The Diagnosis and Treatment of Gout. US Pharmacist. 2009; 34(5):40-7.