# Pharmacy Medical Necessity Guidelines: Krystexxa® (pegloticase)

*Effective: January 12, 2021*

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|---|---|---|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | MED/ RX | Department to Review | PRECERT / MM |

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**

All plans except Tufts Health Public Plans:
Precert: 617.972.9409

Tufts Health Public Plans only:
MM: 888.415.9055

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

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

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Krystexxa (pegloticase) is not recommended for the treatment of asymptomatic hyperuricemia.

Gout is a common arthritis caused by deposition of monosodium urate crystals within joints that can also deposit in tissues and the kidneys. Chronic hyperuricemia is the most important risk factor for gout; although asymptomatic hyperuricemia is common and many people never develop gout.

Acute gouty arthritis most commonly presents as an excruciating attack of pain at night involving a single joint in the lower extremity. Inflammation of the first metatarsophalangeal joint is classically termed podagra. Without treatment the initial acute gout attack generally resolves within a few days. Subsequent attacks frequently last longer and may spread to the upper limbs. Gout usually presents as a monoarthritis of the lower extremities, with pain, erythema, and swelling of the joints.

Diagnosis of gout is based on symptom presentation and confirmed by the presence of monosodium urate crystals upon aspiration of synovial joint fluid. Despite low mortality associated with gout, untreated acute attacks can lead to chronic tophaceous gout characterized by tophi, chronic polyarticular involvement with low-grade joint inflammation, and joint deformity. Studies have also linked hyperuricemia with comorbidities such as hypertension, obesity, renal disease, metabolic syndrome, and cardiovascular.

Goals of treatment for gout include symptom control during an acute attack, risk factor modification, and pharmacotherapy to prevent recurrent attacks and chronic sequela. There is consensus that achievement and maintenance of serum (SUA) levels below the limit of urate solubility in extracellular fluids is necessary for long-term treatment success in patients with persistent or progressive gout. The accepted goal range of SUA for maintenance in clinical studies and evidence-based guidelines is less than 6 mg/dL.

## COVERAGE GUIDELINES

The plan may authorize coverage of Krystexxa (pegloticase) for members, when all of the following criteria are met:

1. Documented diagnosis of chronic gout refractory to conventional therapy meeting at least one of the following criteria:

a. Three or more flares in the past 18 months
b. One or more tophi
c. Chronic gouty arthritis

**AND**

2. Documented baseline serum uric acid level of more than 6 mg/dL

**AND**

3. The prescribing physician is a rheumatologist

**AND**

4. The Member has failed to achieve symptom control after an adherent trial at maximum therapeutic dose for at least three months of BOTH of the following, unless contraindicated or intolerant:
   a. allopurinol
   b. Uloric

## LIMITATIONS

- The plan does not cover Krystexxa (pegloticase) for asymptomatic hyperuricemia.

## CODES

The following HCPCS/CPT code(s) are:

| Code | Description |
|---|---|
| J2507 | Injection, pegloticase, 1 mg |

## REFERENCES


1. 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.
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. Chohan S, Becker MA. Update on emerging urate-lowering therapies. *Curr Opin Rheumatol* 2009; 21:143-149.
4. Conway N, Schwartz S. Diagnosis and management of acute gout. *Med Health RI* 2009; 92(11):356-358.
5. Eggebeen AT. Gout: an update. *Am Fam Physician*. 2007; 76(6):801-8.
6. Krystexxa (pegloticase) [package insert]. Lake Forest, IL: Horizon Pharma Rheumatology LLC; July 2018.
7. Richette P, Bardin T. Gout. *Lancet*. 2010; 375(9711):318-328.
8. Sachs L, Batra KL, Zimmerman B. Medical implications of hyperuricemia. *Med Health RI* 2009; 92(11):353-355.
9. Smith RG. The Diagnosis and Treatment of Gout. *US Pharmacist*. 2009; 34(5):40-7.
10. Strand V, Khanna D, Singh JA et al. Improved health-related quality of life and physical function in patients with refractory chronic gout following treatment with pegloticase: evidence from phase III randomized controlled trials. *J Rheumatol*. 2012 Jul; 39(7):1450-7.
11. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. *JAMA*. 2011 Aug 17; 306(7):711-20.
12. Zhang W, Doherty M, Pascual E, et al. EULAR evidence based recommendations for gout. Part 1: diagnosis. Report of a task force of the Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). *Ann Rheum Dis*. 2006; 65:1301-11.
13. Zhang W, Doherty M, Pascual E, et al. EULAR evidence based recommendations for gout. Part II: Management. Report of a task force of the Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). *Ann Rheum Dis*. 2006; 65:1312-14.


## APPROVAL HISTORY

March 8, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2012: Administrative Update: Replaced HCPCS code C9281 with J2507
2. March 13, 2012: No changes.
3. February 12, 2013: No changes.
4. November 5, 2013: No changes.
5. November 4, 2014: No changes.
6. November 10, 2015: No changes.

7. January 1, 2016: Administrative change to rebranded template
8. April 1, 2016: Added Tufts Health Together – A MassHealth Plan to Medical Necessity Guideline.
9. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
10. February 13, 2018: No changes.
11. February 12, 2019: No changes.
12. March 10, 2020: No changes.
13. January 12, 2021: No changes.

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.