Pharmacy Medical Necessity Guidelines: Krystexxa® (pegloticase)

Effective: February 13, 2018

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<th>Prior Authorization Required</th>
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<th>Type of Review – Care Management</th>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
- All plans except Tufts Health Public Plans:
  - Precert: 617.972.9409
- Tufts Health Public Plans only:
  - MM: 888.415.9055

**Note:** For Tufts Health Plan Medicare Preferred members, refer to the Tufts Health Plan Medicare Preferred prior authorization criteria. Background, applicable product and disclaimer information can be found on the last page.

**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. Approximately three million people in the United States suffer from gout; and of these three million, up to 3% suffer from gout that is refractory to conventional therapy. The prevalence of gout is much higher in men than in women and increases with age especially in association with alcohol and dietary excess. Medications including diuretics and cyclosporine can also contribute to the development of hyperuricemia. 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 sequelae. 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

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

CODES

The following HCPCS/CPT code(s) are:

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<th>Code</th>
<th>Description</th>
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<td>J2507</td>
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REFERENCES


APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:
January 1, 2012: Administrative Update: Replaced HCPCS code C9281 with J2507
March 13, 2012: No changes
February 12, 2013: No changes
November 5, 2013: No changes
November 4, 2014: No changes
November 10, 2015: No changes
January 1, 2016: Administrative change to rebranded template
April 1, 2016: Added Tufts Health Together – A MassHealth Plan to Medical Necessity Guideline.
February 13, 2018: 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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, refer to Tufts Health Plan Medicare Preferred prior authorization criteria.

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.