Pharmacy Policy

Krystexxa (pegloticase)

Policy Number: 9.108
Version Number: 2
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Krystexxa (pegloticase)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Treatment of asymptomatic hyperuricemia Indications other than hyperuricemia with gout
Required Medical Information	1. A diagnosis of chronic refractory gout meeting at least one of following criteria: a. Chronic gouty arthritis b. Presence of gout tophus c. Indication of 3 or more flares in the past 18 months; **AND** 2. Provider attestation that serum uric acid levels greater than 6mg/dL; **AND** 3. One of the following: a. An intolerance, contraindication or inadequate response to a 3 month trial of allopurinol and Uloric® at the maximum effective dose; **OR**

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	b. Member has severe tophaceous disease
Age Restriction	18 years or older
Prescriber Restriction	Prescribed by or in collaboration with a rheumatologist
Coverage Duration	1 year
Quantity Limit	2 vials per 28 days
Other criteria	Reauthorization: 1. Initial criteria has been met 2. Clinical response evidenced by provider attestation that there has been a reduction in serum uric acid levels compared to baseline, and that consecutive serum uric acids levels are less than 6mg/dL.

Applicable Coding:

Code	Medication
J2507	Krystexxa (pegloticase)

Clinical Background Information and References

1. Becker MA, Schumacher HR, Wortmann RL et al. Febuxostat compared with allopurinol in patients with hyperuricemia and gout. N Engl J Med 2005;353:2450-61.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically.
3. Uloric® (febuxostat tablets). [Package Insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; September 2012.
4. Reinders MK, Jansen TL et al. New advances in the treatment of gout: review of pegloticase. Therapeutics and Clinical Risk Management 2010:6 543-550
5. Burns CM, Wortmann RL. Gout therapeutics: new drugs for an old disease. Lancet 2011; 377:165-77
6. Clinical Drug Information, LLC [Internet Database]. Indianapolis, IN: Facts & Comparisons. Updated periodically
7. KRYSTEXXA® (pegloticase injection). [Package Insert]. Lake Forest, IL: Horizon Pharma Rheumatology LLC.; July 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
09/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
9/10/2020	9.105 Anti Gout Medications Policy retired, new policy created. Renamed Krystexxa after Duzallo is removed from policy, added tophaceous disease	1/1/2020	P&T Committee
8/12/2021	Annual P&T Review: reorganized for clarity, added 'initial criteria has been met' to reauthorization requirements	1/1/2022	P&T Committee

Next Review Date

8/2022

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.