Pharmacy Policy

Anti-Gout Medications

Policy Number: 9.105
Version Number: 10.0
Version Effective Date: 01/01/2018

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tr>
<td>☒ New Hampshire Medicaid</td>
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<tr>
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Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan will authorize coverage of Uloric® and Krystexxa™ when appropriate criteria are met.

Description of Item or Service

Uloric®

Febuxostat is a non-purine xanthine oxidase inhibitor with an FDA indication for hyperuricemia in adult patients with gout, and it is not recommended for the treatment of asymptomatic hyperuricemia. It’s one of the first anti-gout medications to be approved in the last 40 years. The pathophysiology of gouty attacks is due to a deposit in uric acid crystals from supersaturated fluids in joints. The goal of therapy is to reduce serum urate levels to prevent further gouty attacks either by decreasing formation of uric acid with xanthine oxidase inhibitors (i.e. febuxostat, allopurinol), or by increasing excretion of uric acid with uricosuric agents such as probenecid.

The FACT trial studied the decrease in serum uric acid level to below 6.0mg/dL and reduction in incidence of gout flares in patients taking allopurinol or febuxostat 80mg for 52 weeks. Although febuxostat subjects showed statistically significant reductions in serum uric acid levels compared to allopurinol, there was no
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**Anti-Gout Medications**

Febuxostat is thought to have fewer effects on other enzymes involved in purine and pyrimidine metabolism than allopurinol, a purine analog. Therefore, febuxostat provides another option for patients that do not respond to or are unable to tolerate allopurinol.

**Krystexxa™ (pegloticase)**

Pegloticase is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. It lowers serum uric acid by catalyzing the oxidation of uric acid to allantoin, which is an inert, water soluble purine that is renally excreted. 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. Pegloticase is not recommended for the treatment of asymptomatic hyperuricemia, and it is contraindicated in patients with Glucose-6-phosphate dehydrogenase (G6PD) deficiency.

In two randomized double-blind placebo controlled trials, pegloticase 8mg IV every 2 weeks was shown to decrease plasma urate levels from ≥ 8mg/dL to < 6mg/dL and completely resolve at least one tophus in higher number of the patients compared to placebo. There was also a high incidence of anti-pegloticase antibodies in nearly 90% of those receiving the drug thereby lowering the effect of pegloticase and increasing risk of infusion reactions. Pegloticase must be administered in a healthcare setting by a healthcare professional prepared for the immediate treatment of anaphylaxis. Premedication with antihistamines and/or corticosteroids is required to minimize anaphylaxis and infusion reactions.

**Policy**

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<tr>
<th>Medication</th>
<th>BMC HealthNet Plan</th>
<th>Well Sense Health Plan</th>
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<tr>
<td></td>
<td>MassHealth</td>
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<tr>
<td>Uloric</td>
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<tr>
<td>Krystexxa</td>
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</table>

The Plan may authorize coverage of Uloric® and Krystexxa™ for members meeting the following clinical criteria:

**Prior Authorization**

A prior authorization request will be required for all prescriptions for Uloric® and Krystexxa™. These requests will be approved when the following criteria are met:

**Uloric (Approval Duration – maximum of 2 years, contingent therapy applies)**

Documentation of the following:

1. A diagnosis of hyperuricemia with gout; **AND**
2. An inadequate response to a trial of the maximum tolerated dose of allopurinol within the previous 120 days; **OR**

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An allergy to generic allopurinol (must document type of allergic reaction)

**Krystexxa**™ (Approval Duration – Maximum of 6 months)

**Initial Therapy**

Documentation of the following:
1. A diagnosis of chronic refractory gout meeting at least one of following criteria:
   - Chronic gouty arthritis
   - Presence of gout tophus
   - Indication of 3 or more flares in the past 18 months; **AND**
2. Serum uric acid levels greater than 6mg/dL; **AND**
3. An intolerance, contraindication or inadequate response to a 3 month trial of allopurinol and Uloric® at the maximum effective dose; **AND**
4. The medication is prescribed by or in consultation with a Rheumatologist

**Continuation of Therapy**

1. Documentation of clinical response evidenced by a reduction in serum uric acid levels compared to baseline, and that consecutive serum uric acids levels are less than 6mg/dL.

**Applicable Coding**

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<tr>
<th>J Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2507</td>
<td>pegloticase</td>
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**Limitations**

The Plan will **not** approve coverage of Uloric® or Krystexxa™ in the following instances:

- When the above criteria are not met.
- Treatment of asymptomatic hyperuricemia
- Indications other than hyperuricemia with gout

**Clinical Background Information and References**


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<table>
<thead>
<tr>
<th>Original Approval Date</th>
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<th>Policy Owner</th>
<th>Approved by</th>
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<tr>
<td>09/10/2009</td>
<td>09/10/2009</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee</td>
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### Policy Revisions History

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<th>Summary of Revisions</th>
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<tr>
<td>09/16/2010</td>
<td>P&amp;T Annual Review, renamed policy “Anti-Gout Medications”, removed uric acid level requirement</td>
<td>01/01/2011</td>
<td>P&amp;T Committee</td>
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<tr>
<td>09/08/2011</td>
<td>P&amp;T Annual Review, criteria added for Krystexxa, policy applied to Commercial</td>
<td>01/01/2012</td>
<td>P&amp;T Committee</td>
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<tr>
<td>08/22/2012</td>
<td>Policy applied to NH Medicaid</td>
<td>12/01/2013</td>
<td>P&amp;T Committee, NH DHHS</td>
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<tr>
<td>09/13/2012</td>
<td>P&amp;T Annual Review, rephrased initial criteria for Krystexxa™</td>
<td>01/01/2013</td>
<td>P&amp;T Committee, NH DHHS</td>
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<tr>
<td>09/12/2013</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>01/01/2014</td>
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<tr>
<td>12/13/2013</td>
<td>P&amp;T annual review, Policy applied to ConnectorCare/Qualified Health Plan</td>
<td>04/01/2014</td>
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<tr>
<td>09/11/2014</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>01/01/2015</td>
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<tr>
<td>09/10/2015</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>01/01/2016</td>
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<td>09/08/2016</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>01/01/2017</td>
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<td>09/14/2017</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>01/01/2018</td>
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### Next Review Date

09/13/2018

### Other Applicable Policies

9.002 Mandatory Generic Substitution Policy
9.015 Quantity Limitation Policy
OCA 3.14 Medically Necessary Policy

### Reference to Applicable Laws and Regulations, If Any

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**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.

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