## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Krystexxa (pegloticase)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J2507</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient</td>
</tr>
<tr>
<td>STATUS</td>
<td>Prior Authorization Required</td>
</tr>
</tbody>
</table>

Krystexxa (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. According to the American College of Rheumatology guideline for management of gout, pegloticase should not be a first-line therapy. Pegloticase is recommended for patients with gout for whom xanthine oxidase inhibitor treatment, uricosurics, and other interventions have failed to achieve the serum uric acid target, and who continue to have frequent gout flares or who have non-resolving subcutaneous tophi.

Krystexxa (pegloticase) will be considered for coverage when the following criteria are met:

### Chronic Gout

**For initial authorization:**

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a diagnosis of chronic gout with 2 or more flares per year OR with non-resolving subcutaneous tophi associated with gout; AND
4. Member has had inadequate response (defined as serum uric acid (sUA) level remains above 6 mg/dL), or contraindication to, at least 3 months of both of the following:
   a) A xanthine oxidase inhibitor (e.g., allopurinol (Zyloprim) or febuxostat (Uloric)) at maximally appropriate dose. Note: allopurinol is first-line (typically 300 to 800 mg/day) and
   b) A uricosuric agent (e.g., probenecid); AND
5. Krystexxa will be co-administered with methotrexate unless contraindicated or not tolerated; AND
6. Other urate lowering therapy (i.e., allopurinol, febuxostat, probenecid, lesinurad) will be discontinued; AND
7. Member does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency per screening result.

8. **Dosage allowed/Quantity limit:** 1 single-dose vial (8 mg) given as an intravenous infusion every 2 weeks, co-administered with weekly methotrexate 15 mg.
   QL: 2 vials per 28 days

*If all the above requirements are met, the medication will be approved for 6 months.*

**For reauthorization:**

1. Member’s serum uric acid (sUA) level has maintained below 6 mg/dL; AND
2. Chart notes demonstrate a positive clinical outcome from using medication (e.g., reduction of flares, reduction of tophi).

*If all the above requirements are met, the medication will be approved for an additional 12 months.*
CareSource considers Krystexxa (pegloticase) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>04/06/2021</td>
<td>New policy for Krystexxa (pegloticase) created.</td>
</tr>
<tr>
<td>07/28/2022</td>
<td>Transferred to new template. Updated and added references. Removed nephrology, podiatry specialists. Corrected sUC to sUA. Added QL. Added must be given with methotrexate (new labeling). Added not to be used with other urate lowering drugs. Added example dosing to first line allopurinol.</td>
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</tbody>
</table>

References:


Effective date: 01/01/2023
Revised date: 07/28/2022