PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Berinert (C1 esterase inhibitor (human))</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J0597</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home/Office/Outpatient</td>
</tr>
<tr>
<td>STATUS</td>
<td>Prior Authorization Required</td>
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</tbody>
</table>

Berinert is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients. HAE is a rare autosomal dominant disease characterized by episodic unpredictable swelling, which can occur in a variety of anatomic locations. The swelling results from excess production of the vasodilator bradykinin. Attacks may be painful and cause functional impairment but are not associated with pruritis. The most common types of HAE are caused by deficiency (type 1) or dysfunction (type 2) of C1 inhibitor (C1-INH). Type 1 is the most prevalent.

Berinert (C1 esterase inhibitor (human)) will be considered for coverage when the following criteria are met:

**Hereditary Angioedema**

For *initial* authorization:
1. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
2. Member has a diagnosis of HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
3. Medication is being prescribed for the treatment of *acute* HAE attacks; AND
4. Member has documented trial and failure of or contraindication to icatibant (if 18 years of age or older)
5. Medication is not being used in combination with another acute HAE therapy (e.g., Kalbitor, Firazyr, Ruconest).
6. **Dosage allowed/Quantity limit**: 20 International Units (IU) per kg body weight by IV injection.
   
   QL: 8 vials per fill

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

For *reauthorization*:
1. Chart notes must document improvement such as faster time to symptom relief or resolution of attack.

*If all the above requirements are met, the medication will be approved for an additional 12 months.*

CareSource considers Berinert (C1 esterase inhibitor (human)) 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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</thead>
<tbody>
<tr>
<td>08/25/2017</td>
<td>New policy for Berinert created. Criteria for each type of HAE specified. Criteria of documentation of attacks, discontinuation of meds that can cause HAE, and restriction on combinations with other meds for acute attacks were added.</td>
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<tr>
<td>06/29/2022</td>
<td>Transferred to new template. Updated references. Added pharmacy as benefit option. Added trial of icatibant for adults.</td>
</tr>
</tbody>
</table>

References:


Effective date: 01/01/2023
Revised date: 06/29/2022