PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Adakveo (crizanlizumab-tmca)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J0791 (1 unit = 5 mg)</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Outpatient Hospital/Office/Infusion Site</td>
</tr>
<tr>
<td>STATUS</td>
<td>Prior Authorization Required</td>
</tr>
</tbody>
</table>

Adakveo was approved by the FDA in 2019. It is indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease. Adakveo may be given with or without hydroxyurea.

Sickle cell disease is caused by an inherited mutation in the beta globin gene, resulting in abnormal hemoglobin called sickle hemoglobin (HbS). Red blood cells become rigid, undergo premature hemolysis leading to anemia, and become unable to transport oxygen to critical organs. Patients experience severe pain from vaso-occlusive crises. First line therapy for sickle cell disease is hydroxyurea.

Adakveo binds to P-selectin and blocks interactions with its ligands, including P-selectin glycoprotein ligand 1 (PSGL-1). It can also dissociate preformed Pselectin/PSGL-1 complex. Binding P-selectin on the surface of the activated endothelium and platelets blocks interactions between endothelial cells, platelets, red blood cells, and leukocytes.

Adakveo (crizanlizumab-tmca) will be considered for coverage when the following criteria are met:

**Sickle Cell Disease**

For **initial** authorization:
1. Member must be 16 years of age or older; AND
2. Medication must be prescribed by or in consultation with a hematologist or a physician who has experience in treating sickle cell disease; AND
3. Member has a documented diagnosis of sickle cell disease with at least 2 vaso-occlusive pain crises in the past 12 months; AND
4. Member has tried hydroxyurea for at least 3 months and it was ineffective or not tolerated; AND
5. Medication will not be used concurrently with Oxbryta (voxelotor) therapy.
6. **Dosage allowed/Quantity limit:** 5 mg/kg intravenously at week 0, week 2, and every 4 weeks thereafter.

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

For **reauthorization**:
1. Chart notes have been provided to show that the member has experienced a reduction in frequency of vaso-occlusive crises since starting treatment.

*If all the above requirements are met, the medication will be approved for an additional 12 months.*
CareSource considers Adakveo (crizanlizumab-tmca) 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>04/17/2020</td>
<td>New policy for Adakveo created.</td>
</tr>
<tr>
<td>06/18/2020</td>
<td>New J Code added</td>
</tr>
<tr>
<td>08/21/2020</td>
<td>Removed Endari from trial requirement.</td>
</tr>
<tr>
<td>02/21/2022</td>
<td>Transferred to new template. Removed “all initial criteria” from reauth. Added diagnosis of sickle cell to pain crisis criteria. Modified wording of hydroxyurea trial to match Oxbryta policy.</td>
</tr>
</tbody>
</table>

References:


Effective date: 07/01/2022
Revised date: 02/21/2022