PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Takhzyro (lanadelumab-flyo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J0593</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home/Office</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
</tr>
<tr>
<td></td>
<td>Alternative preferred product: Haegarda</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>2 vials (300 mg/2 ml per vial) per 28 days</td>
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</tbody>
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LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY

Takhzyro (lanadelumab-flyo) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**HEREDITARY ANGIOEDEMA (HAE)**

For **initial authorization:**
1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. 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
4. Chart notes must document the member’s baseline frequency of HAE attacks; AND
5. Member is inadequately controlled with on-demand treatment alone; AND
6. Takhzyro is being prescribed for ongoing prophylaxis and will not be used to treat acute attacks; AND
7. Member has a trial and failure of or contraindication to Haegarda.
8. **Dosage allowed:** 300 mg subQ every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months.

*If member meets all the requirements listed above, the medication will be approved for 6 months.*

For **reauthorization**:
1. Chart notes must be provided that show a reduced rate of HAE attacks since starting treatment.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

CareSource considers Takhzyro (lanadelumab-flyo) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acquired angioedema (AAE)
Treatment of acute HAE attacks

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/06/2019</td>
<td>New policy Takhzyro created.</td>
</tr>
<tr>
<td>01/13/2021</td>
<td>Updated criteria to align with the other HAE prophylactic drug revisions. Updated references. Greatly simplified the diagnostic confirmation criteria. Removed minimum required number of attacks, per guidelines; will just ask for baseline measure. Removed the statement about causative medications. Added that they must try on-demand treatment first. Rewrote the renewal criteria and removed log book requirement. Extended initial auth duration to 6 mo and renewal to 12 mo. Corrected the J code for billing.</td>
</tr>
</tbody>
</table>

References:


Effective date: 07/01/2021
Revised date: 01/13/2021