### PHARMACY POLICY STATEMENT

**Ohio Medicaid**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Givlaari (givosiran)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J3490 (1 unit = 1 mL)</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>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>— based on weight</td>
</tr>
<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
</tr>
</tbody>
</table>

Givlaari (givosiran) 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.

### ACUTE HEPATIC PORPHYRIA (AHP)

**For initial authorization:**
1. Member is 18 years old or older; **AND**
2. Medication must be prescribed by or in consultation with a gastroenterologist, a hepatologist, or a physician who has experience with treating acute hepatic porphyria; **AND**
3. Member has a confirmed diagnosis of Acute Hepatic Porphyria with one of the following types: Acute Intermittent Porphyria, Hereditary Corproporphyria, Variegate Porphyria, aminolevulinic acid (ALA) dehydratase deficient porphyria; **AND**
4. Member has had at least 2 porphyria attacks within the last 6 months documented in chart notes (Note: attacks are defined as requiring hospitalization, urgent care visit, or intravenous hemin administration at home); **AND**
5. Member does not have ANY of the following:
   a) Prior or anticipated liver transplant;
   b) Active HIV infection;
   c) Active Hepatitis B or C virus; **AND**
6. Member will not be receiving prophylactic treatment with intravenous Panhematin (IV hemin) while taking Givlaari (Note: acute use of Panhematin for the treatment of an attack is allowed).
7. **Dosage allowed:** 2.5mg/kg via subcutaneous injection once monthly.

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

**For reauthorization:**
1. Member has not been using prophylactic Panhematin while taking Givlaari; **AND**
2. Member is in compliance with all other initial criteria; **AND**
3. Chart notes have been provided to show the member has had a reduction in the number of porphyria attacks.

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

CareSource considers Givlaari (givosiran) not medically necessary for the treatment of the diseases that are not listed in this document.
DATE | ACTION/DESCRIPTION
--- | ---
04/23/2020 | New policy for Givlaari created.

References:

Effective date: 05/25/2020
Revised date: 04/23/2020