CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Givlaari (givosiran)
BILLING CODE	J3490 (1 unit = 1 mL)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— based on weight
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Givlaari (givorisan) 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 Corproporhyria, 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:

1. Givlaari [package insert]. Summit, NJ: Celgene Corporation, November 2019.
2. ENVISION: A Study to Evaluate the Efficacy and Safety of Givosiran (ALN-AS1) in Patients With Acute HepaticPorphyrias (AHP). Clinicaltrials.gov. Accessed April 23, 2020.
3. Balwani M, Wang B, Anderson KE, et al. Acute hepatic porphyrias: Recommendations for evaluation and long-term management. Hepatology. 2017;66(4):1314–1322. doi:10.1002/hep.29313.
4. Givlaari Drug Approval Package - Multi-Discipline Review, Application Number 212194. Food and Drug Administration Center for Drug Evaluation and Research. Accessed April 23, 2020.

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