**Medical Policy**

| Givlaari® (givosiran) | |
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| **MEDICAL POLICY NUMBER** | Med_Clin_Ops-053 |
| **CURRENT VERSION EFFECTIVE DATE** | January 1, 2024 |
| **APPLICABLE PRODUCT AND MARKET** | *Individual Family Plan:* All Plans<br>*Small Group*: All Plans<br>*Medicare Advantage:* All Plans |

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*If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.*

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## PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Givlaari® (givosiran) therapy.

## POLICY/CRITERIA

## Prior Authorization and Medical Review is required.

Coverage for Givlaari will be provided for 12 months and may be renewed.

### Initial Therapy

1. Patient has a diagnosis of acute hepatic porphyria (including acute intermittent porphyria, hereditary coproporhyria, variegate porphyria, ALA dehydratase deficient porphyria); **AND**
2. Patient is at least 18 years of age; **AND**
3. Givlaari is prescribed by or in consultation with, a porphyria specialist (e.g., hepatologist, gastroenterologist, etc.); **AND**

4. Patient has had elevated urinary or plasma PBG (porphobilinogen) or ALA (aminolevulinic acid) values within the past year; **AND**
5. Clinical presentation of disease has been documented (e.g. abdominal pain, constipation, nausea/vomiting, symptoms of ileus, tachycardia, hypertension, dark urine, skin photosensitivity or other cutaneous symptoms, disease-specific common laboratory abnormalities [hyponatremia, hypomagnesemia], seizures, CKD, etc.); **AND**
6. Active disease has been documented with at least 2 porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous hemin administration at home, within the past 6 months

**Continuation Therapy**

1. Prescriber attests to disease response as evidenced by a decrease in the frequency of acute porphyria attacks, and/or hospitalizations/urgent care visits, and/or a decrease requirement of hemin intravenous infusions

## LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

## BACKGROUND

Givlaari (givosiran) is indicated for the treatment of adults with acute hepatic porphyria (AHP). Givosiran is a double-stranded small interfering RNA that causes degradation of aminolevulinate synthase 1 (ALAS1) mRNA in hepatocytes through RNA interference, reducing the elevated levels of liver ALAS1 mRNA. This leads to reduced circulating levels of neurotoxic intermediates aminolevulinic acid (ALA) and porphobilinogen (PBG), factors associated with attacks and other disease manifestations of AHP.

## DEFINITIONS

1. GIVLAARI (givosiran) injection, for subcutaneous use. Initial U.S. Approval: 2019
    a. GIVLAARI (givosiran) is a clear, colorless-to-yellow ready-to-use solution available in single-dose vials of 189 mg/mL in cartons containing one vial

## CODING

| Applicable NDC Codes | |
|---|---|
| 71336-1001-01 | Givlaari (givosiran sodium), 189mg/ml single use vial |

| Applicable Procedure Code | |
|---|---|
| J0223 | Injection, givosiran, 0.5 mg |

| Applicable ICD-10 Codes | |
|---|---|
| E80.20 | Unspecified porphyria |
| E80.21 | Acute intermittent (hepatic) porphyria |
| E80.29 | Other porphyria |

## EVIDENCE BASED REFERENCES

1. Product Information: GIVLAARI(TM) subcutaneous injection, givosiran subcutaneous injection. Alnylam Pharmaceuticals Inc (per FDA), Cambridge, MA, 2019.

### POLICY HISTORY

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| Original Effective Date | May 24, 2021 |
| Revised Date | July 26, 2022: Annual review – no changes made.<br>November 8, 2022: Annual review – no changes made.<br>March 1, 2023 – Adopted by MA UMC – no changes made.<br>January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made) |

Approved by Pharmacy and Therapeutics Committee on 11/8/2022