# SPECIALTY GUIDELINE MANAGEMENT

## GIVLAARI (givosiran)

## POLICY

## I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## **FDA-Approved Indications**

Givlaari is an aminolevulinate synthase 1-directed small interfering RNA indicated for the treatment of adults with acute hepatic porphyria (AHP).

All other indications are considered experimental/investigational and not medically necessary.

## **II. DOCUMENTATION**

Submission of the following information is necessary to initiate the prior authorization review: Elevated porphobilinogen (PBG) in the urine confirmed by a PBG quantitative, random urine test, or an elevated porphyrin level (plasma or fecal).

## **III. CRITERIA FOR INITIAL APPROVAL**

## Acute Hepatic Porphyria

Authorization of 12 months may be granted for treatment of acute hepatic porphyria when all of the following criteria are met:

- 1. The member is actively symptomatic
- 2. The member has an elevated urine porphobilinogen (PBG), or an elevated porphyrin level (plasma or fecal).

## **IV. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continued treatment of an indication listed in Section III for members who are experiencing benefit from therapy while receiving Givlaari.

## V. REFERENCES

1. Givlaari [package insert]. Cambridge, MA: Alnylam Pharmaceuticals; November 2019.

Givlaari 3418-A SGM P2019.docx

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