Reference number(s)
3418-A

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.