Reference number(s)
4235-A

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
For initial requests: 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Givlaari.
B. Givlaari is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy.

V. REFERENCES

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