Reference number(s)
3418-A

Specialty Guideline Management
Givlaari

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Givlaari	givosiran

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 indicated for the treatment of adults with acute hepatic porphyria (AHP).

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

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).

Coverage Criteria

Acute Hepatic Porphyria

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

- The member is actively symptomatic (e.g., porphyria attacks requiring hospitalization, urgent healthcare visits, or intravenous hemin administration), or the member has experienced 4 or more porphyria attacks per year.
- The member has an elevated urine porphobilinogen (PBG), or an elevated porphyrin level (plasma or fecal).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of an indication listed in the coverage criteria section for members who are experiencing benefit from therapy while receiving Givlaari (e.g., reduction in porphyria attacks that required hospitalizations, urgent healthcare visit, or intravenous hemin administration).

References

1. Givlaari [package insert]. Cambridge, MA: Alnylam Pharmaceuticals; April 2024.