Reference number(s)
4235-A

Standard Medicare Part B 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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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).

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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

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:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication enumerated in coverage criteria section.
- The member is receiving benefit from therapy (e.g., reduction in porphyria attacks that required hospitalizations, urgent healthcare visit, or intravenous hemin administration).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Givlaari.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Givlaari are covered.

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Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information and the ENVISION trial cited in the prescribing information.

References

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

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