RX.PA.091.MPC Givlaari (givosiran)

PURPOSE

The purpose of this policy is to define the prior authorization process for Givlaari (givosiran).

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

PROCEDURE

A. Initial Authorization Criteria:

**Please note that the provider must submit clinical documentation (chart notes, laboratory results and any other clinical support).*

Must meet all of the criteria listed under the respective diagnosis:

1. Acute Hepatic Porphyria (AHP). Approve for 3 months if the patient meets **ALL** the following:

- Patient is ≥ 18 years of age
- Patient has a diagnosis of Acute Hepatic Prophyria (AHP)
  - Acute Intermittent Prophyria
  - Hereditary Corproporhyria
  - Variegate Prophyria
  - Aminolevulinic Acid Dehyratase Deficient Prophyria
- Patient has elevated urinary or plasma porphobilinogen (PBG) or ALA values within the last year
- Must provide the following laboratory documentation drawn within 30 days of requesting authorization:
  - Negative HIV
  - Negative Hepatitis C infection
  - Negative Hepatitis B infection
- Patient has not had, nor is anticipating, a liver transplant
- Patient has active disease with at least 2 documented porphyria attacks within the last 6 months requiring 1 of the following:
  - Hospitalization
  - Urgent care visit
  - IV hemin administration
- Female patients must have a documented negative pregnancy test drawn within 30 days of requesting authorization

- Provider attests that Panhematin will not be utilized concurrently with Givlaari
- Must be prescribed by a hematologist, gastroenterologist or neurologist

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Givlaari will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria</u>

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member is still a candidate for treatment with the requested product based upon the prescriber's assessment while on therapy.
- Provider attests that the patient has not had, nor is anticipating, a liver transplant
- Chart documentation that member is responding to treatment as evidenced by:
  - Improvement in the symptoms of AHP from baseline
  - Reduction in the number of porphyria attacks
  - Reduction in Hemin utilization

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC) and have been taking Givlaari, or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).AND
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment
- Chart documentation that member is responding to treatment as evidenced by:
  - Improvement in the symptoms of AHP from baseline
  - Reduction in the number of porphyria attacks
  - Reduction in Hemin utilization

<u>Limitations:</u>

Length of Authorization (if above criteria met)	
Initial Authorization	3 months
Reauthorization	12 months

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J0223	Injection, givosiran, 0.5mg

REFERENCES

1. Givlaari® [prescribing information]. San Diego, CA: Ajinomoto Althea, Inc; February 2023.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*02/2024*