Gateway Health℠ It's Wholecare.

Updated: 07/2021
PARP Approved: 07/2021

Prior Authorization Criteria
Givlaari (givosiran)

All requests for Givlaari (givosiran) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of acute hepatic porphyria (AHP) and the following criteria is met:

- Member must be 18 years of age or older
- Must be prescribed by or in consultation with a provider who specializes in porphyria (i.e. hematologist, hepatologist, gastroenterologist)
- Member must have active disease defined as having at least 2 documented porphyria attacks requiring hospitalization, urgent care visits, or IV hemin administration within the last 6 months.
- Documentation the members has had elevated urinary or plasma porphobilinogen (PBG) or aminolevulinic acid (ALA) levels with the past year (reference range must be provided)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation from the prescriber indicating stabilization or improvement in the member's condition since starting the medication.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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GIVLAARI (GIVOSIRAN)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Acute Hepatic Porphyria (AHP) ☐ Other: _____ ICD-10 Code: _____

Has the member had 2 or more porphyria attacks in the last 6 months that required at least one of the following: a hospitalization, an urgent care visit, or IV hemin administration? ☐ Yes ☐ No

Please provide one of the following labs and reference range:

Urinary or plasma porphobilinogen (PBG): _____ reference range: _____ date taken: _____

Aminolevulinic acid level (ALA): _____reference range:_____ date taken:_____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a stabilization or improvement with treatment? ☐ Yes ☐ No

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date