

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.

For all requests for Givlaari (givosiran) all of the following criteria must be met:

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.

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 Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

| | |
|----------------------|-----------------|
| Requesting Provider: | Provider NPI: |
| Provider Specialty: | Office Contact: |
| State license #: | Office NPI: |
| Office Address: | Office Phone: |
| | Office Fax: |

MEMBER INFORMATION

| | |
|--------------|------------------------|
| Member Name: | DOB: |
| Member ID: | Member weight: Height: |

REQUESTED DRUG INFORMATION

| | |
|---|--------------------|
| Medication: | Strength: |
| Directions: | Quantity: Refills: |
| Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated: | |

Billing Information

| |
|--|
| This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE: |
| Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other |

Place of Service Information

| | |
|----------|--------|
| Name: | NPI: |
| Address: | Phone: |

MEDICAL HISTORY (Complete for ALL requests)

| | |
|--|-----------|
| Diagnosis: | ICD 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? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Please describe: |

SUPPORTING INFORMATION or CLINICAL RATIONALE

| |
|--|
| |
| |

Prescribing Provider Signature

Date

| | |
|--|--|
| | |
|--|--|



Updated: 06/2024
PARP Approved:06/2024