

Givosiran (Givlaari®)

**Place of Service**  
Hospital Administration  
Office Administration  
Infusion Center Administration  
  
HCPCS: J0223 per 0.5 mg

**Condition listed in policy (see criteria for details)**

- [Acute hepatic porphyria \(AHP\)](#)

**AHFS therapeutic class:** Hematologic agent for acute hepatic porphyria

**Mechanism of action:** Aminolevulinic acid synthase 1 (ALAS1)-directed small interfering RNA

**(1) Special Instructions and pertinent Information**

**Covered under the medical benefit,** please submit clinical information for prior authorization review.

**(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for givosiran (Givlaari®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**Acute hepatic porphyria (AHP)**

1. Diagnosis confirmed by elevated aminolevulinic acid (ALA) and porphobilinogen (PBG) levels based on lab results, **AND**
2. Age 18 years or older

**Covered Doses**

Up to 2.5 mg/kg SC once monthly

**Coverage Period**

Indefinitely

**ICD-10:**

E80.20, E80.21, E80.29

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for givosiran (Givlaari®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- 189 mg/mL solution in a single-dose vial

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>

- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Givlaari® (givosiran) [Prescribing information]. Cambridge, MA.: Alnylam Pharmaceuticals, Inc.; 2/2023.

### **(7) Policy Update**

Date of last revision: 3Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*