blue california
Promise Health Plan

givosiran (Givlaari)

Medical Benefit Drug Policy

Place of Service
Hospital Administration
Infusion Center Administration
Office Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Aminolevulinate synthase 1 (ALAS1)-directed small interfering RNA
HCPCS:
J0223:Injection, givosiran, 0.5 mg
How Supplied:
189 mg/mL single-dose vial

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

- Acute Hepatic Porphyria (AHP)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Acute Hepatic Porphyria (AHP)
Meets medical necessity if all the following are met:
1. Diagnosis confirmed by elevated aminolevulinic acid (ALA) and porphobilinogen (PBG) levels based on lab results
2. Age 18 years or older

Covered Doses:
Up to 2.5 mg/kg given subcutaneously once monthly

Coverage Period:

Indefinite

ICD-10:
E80.20, E80.21, E80.29

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Givlaari (givosiran) Prescribing Information. Alnylam Pharmaceuticals, Inc.; Cambridge, MA: 4/2024.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee