givosiran (Givlaari)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

Blue Shield of California is an independent member of the Blue Shield Association

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF GIVLAARI IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving the first dose of Givlaari or is being re-initiated on Givlaari after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Givlaari based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Givlaari based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Number 2: severe adverse events may include anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure, etc.

Number 3: may also include a history of adverse events not mitigated by premedication where the physician is uncomfortable administering the drug in a home or ambulatory setting

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