Givosiran (GIVLAARI)
Criteria for Use
June 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to the item below is met, then the patient is NOT eligible for givosiran.

☐ History of or anticipated liver transplantation

Inclusion Criteria

Must fulfill ALL of the following to be eligible for givosiran.

☐ Restricted to VA / VA Community Care provider in dermatology, gastroenterology, gynecology, hematology, hepatology, or neurology, or in consultation with one of these specialties

☐ Diagnosis of acute hepatic porphyria by at least ONE of the following:

- ☐ Genetic testing confirming mutation for acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, or aminolevulinic acid (ALA) dehydratase deficient porphyria

OR

- ☐ Confirmation of acute hepatic porphyria by documentation of clinical features (e.g., severe abdominal pain or other neurovisceral symptoms) and laboratory parameters (e.g., urinary or plasma porphobilinogen [PBG] or ALA at least four times the upper limit normal) during an acute attack

☐ Active disease with at least 2 porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous hemin administered within the past 6 months despite avoidance of potential precipitating factors* AND intravenous hemin prophylaxis administered more than once weekly or documented intolerance to hemin

☐ For women with menstrual cycle-related attacks, intolerance to or ineffective prophylaxis with a gonadotropin-releasing hormone analogue

*Patient should be counseled on factors that could increase the risk for attacks including certain medications, smoking, alcohol, and dietary factors; referral to a dietitian for consultation should also be considered, if not already involved in care

Note: Evaluate for continuation of therapy based on patient response as evidenced by improvement (e.g., reduction in number of attacks requiring hospitalization, urgent care visit, or administration of intravenous hemin), disease stabilization or absence of disease progression, and ability to tolerate treatment.