

GIVLAARI MEDICATION ORDER

Patient's Name (Last, First, Middle) _____ DOB: _____

■ Diagnosis

- E80.20 Unspecified porphyria E80.29 Other porphyria
 E80.21 Acute intermittent (hepatic) porphyria Other: _____

■ Details Needed for Authorization

- If the patient is female, is she pregnant? _____ If not, is the patient anticipating getting pregnant while taking Givlaari? _____
- Has the patient had a liver transplant? _____ If not, is the patient anticipating a liver transplant? _____
- Does the patient have elevated urinary or plasma PBG (urinary porphobilinogen) and ALA values within the past year? _____
- Does the patient have a mutation in an affected gene as identified on molecular genetic testing? _____
- Does the patient have active disease, with ≥ 2 porphyria attacks (requiring urgent care or IV hemin) within the last 6 months? _____
- Does the patient have active disease, with ≥ 1 severe porphyria attack with CNS involvement within the last 6 months? _____
- If the patient prophylactically taking hemin while waiting for treatment, will it be discontinued within 3-6 months of starting Givlaari? _____

■ Givlaari Order

Height in ft/in: _____ Weight in lbs: _____

Standard dose:

- Givlaari (givosiran) 2.50 mg/kg administered by subcutaneous injection once monthly for _____ months (6 months maximum).

Dose for patients who have a dose interruption with subsequent improvement:

- Givlaari (givosiran) 1.25 mg/kg administered by subcutaneous injection once monthly for _____ months (6 months maximum).

Follow manufacturer instructions carefully. Medication does not require reconstitution. Using aseptic technique, draw up the calculated dose, expel air bubbles, and inject to designate site(s) subcutaneously. If total volume to administer exceeds 1.5ml, split evenly into two injections. Follow manufacturer's injection instructions, including needle angle, proscripton on aspiration, and waiting prior to withdrawing needle. Check vitals and monitor for signs and symptoms of a reaction throughout.

■ Rescue Management in case of Reaction

These include fever, chills, rigors, headache, rash, itching, swelling, edema, nausea, vomiting, abdominal pain, hypotension, and respiratory distress.

- Follow standing reaction orders, including diphenhydramine, methylprednisolone, albuterol and oxygen as needed.
- For severe reactions, administer Epi-pen or equivalent and call 911. Repeat if severe symptoms persist.
- Call ordering provider to report reaction.

■ Ordering Provider Authorization

Provider's Signature: _____ Name: _____ Date: _____

Address: _____

Phone: _____ Fax: _____ NPI #: _____ License: _____

Best Contact Person in Office: _____ Direct Phone Line to Contact Person: _____

DOCUMENTATION TO INCLUDE:

- Patient demographics and insurance, including card scans (both medical and pharmacy benefit cards, both sides).
- Most recent chart notes and, if available, last history and physical. All relevant scans, tests and laboratory results.
- Chart notes which include decision to begin treatment with Givlaari (givosiran), and notes on recent treatments (if applicable).

Fax this order and supporting documentation to (732) 329-2322.