GIVLAARI®
(givosiran) injection for subcutaneous use
189 mg/mL

PROVIDER READINESS GUIDE

Alnylam Assist® is here to help

Alnylam Assist® is dedicated to helping guide your patients through treatment with GIVLAARI® (givosiran).

Alnylam Assist® offers a range of services to help with:

- Securing access to GIVLAARI for your patient
- Initiating treatment with GIVLAARI for your patient
- Facilitating product orders

For more information about how Alnylam Assist® can help your patients, visit **www.AlnylamAssist.com**.

Preparing for the reimbursement process

When considering whether to offer GIVLAARI to your patients, please refer to the steps below when setting up your office.

With your payers

1. Contact the payers you participate with (commercial, local Medicare Administrative Contractor, State Medicare, etc.) for additional information regarding appropriate coverage, coding, and payment policies for GIVLAARI.
   - Discuss the payment methodology for the appropriate unclassified Healthcare Common Procedure Coding System (HCPCS) code with commercial payers
2. Ensure that the clinical documentation for each patient is in accordance with payer-specific coverage requirements and key medical necessity criteria.

With your practice

3. Know who in your practice is responsible for each of the following tasks:
   - Receiving benefit verification information
   - Submitting prior authorization/precertification, if required
   - Discussing financial obligations with patients
   - Scheduling appointments for GIVLAARI administration
   - Ordering GIVLAARI
   - Submitting claims to payers
4. Update charge master/electronic billing system to ensure that GIVLAARI is recognized.
5. Anticipate requests from payers for clinical documentation if filing claims for GIVLAARI.

The Alnylam Assist® team includes **Field Reimbursement Directors** who are knowledgeable in chart documentation best practices and GIVLAARI billing and coding requirements.

Please see Important Safety Information on page 4 and full Prescribing Information.

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Initiating therapy

When preparing to treat a patient with GIVLAARI® (givosiran) at your practice, follow the steps below to help enable patient access, proper claims submission, and reimbursement.

1. Together with your patient, complete the Alnylam Assist® **Start Form** to initiate verification of benefits and/or an eligibility assessment for patient financial assistance, if required.
   - To access the Alnylam Assist® **Start Form**, visit www.AlnylamAssist.com

To get started, go to **www.AlnylamAssist.com** and complete the Alnylam Assist® **Start Form** with your patient.

2. Schedule the patient's GIVLAARI injection.

3. Work with Alnylam Assist® to determine the method for ordering GIVLAARI.
   - The Alnylam Assist® team will help facilitate acquisition of GIVLAARI for your patient via specialty distributor or specialty pharmacy. For some patients, home injection may also be an option

4. After treatment, complete and submit the claim to the payer.
   - Your practice will have access to **Field Reimbursement Directors** who are available to meet with you and your staff to address reimbursement-related questions related to GIVLAARI

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Alnylam ASSIST®

Monday–Friday, 8AM–6PM ET
: 1-833-256-2748 | : 1-833-256-2747

To learn more about GIVLAARI® (givosiran), visit www.GIVLAARIHCP.com.

INDICATION

GIVLAARI® (givosiran) is indicated for the treatment of adults with acute hepatic porphyria (AHP).

IMPORTANT SAFETY INFORMATION

Contraindications

GIVLAARI is contraindicated in patients with known severe hypersensitivity to givosiran. Reactions have included anaphylaxis.

Anaphylactic Reaction

Anaphylaxis has occurred with GIVLAARI treatment (<1% of patients in clinical trials). Ensure that medical support is available to appropriately manage anaphylactic reactions when administering GIVLAARI. Monitor for signs and symptoms of anaphylaxis. If anaphylaxis occurs, immediately discontinue administration of GIVLAARI and institute appropriate medical treatment.

Hepatic Toxicity

Transaminase elevations (ALT) of at least 3 times the upper limit of normal (ULN) were observed in 15% of patients receiving GIVLAARI in the placebo-controlled trial. Transaminase elevations primarily occurred between 3 to 5 months following initiation of treatment.

Measure liver function tests prior to initiating treatment with GIVLAARI, repeat every month during the first 6 months of treatment, and as clinically indicated thereafter. Interrupt or discontinue treatment with GIVLAARI for severe or clinically significant transaminase elevations. In patients who have dose interruption and subsequent improvement, reduce the dose to 1.25 mg/kg once monthly. The dose may be increased to the recommended dose of 2.5 mg/kg once monthly if there is no recurrence of severe or clinically significant transaminase elevations at the 1.25 mg/kg dose.

Renal Toxicity

Increases in serum creatinine levels and decreases in estimated glomerular filtration rate (eGFR) have been reported during treatment with GIVLAARI. In the placebo-controlled study, 15% of patients receiving GIVLAARI experienced a renally-related adverse reaction. The median increase in creatinine at Month 3 was 0.07 mg/dL. Monitor renal function during treatment with GIVLAARI as clinically indicated.

Injection Site Reactions

Injection site reactions were reported in 25% of patients receiving GIVLAARI in the placebo-controlled trial. Symptoms included erythema, pain, pruritus, rash, discoloration, or swelling around the injection site. One (2%) patient experienced a single, transient, recall reaction of erythema at a prior injection site with a subsequent dose administration.

Drug Interactions

Concomitant use of GIVLAARI increases the concentration of CYP1A2 or CYP2D6 substrates, which may increase adverse reactions of these substrates. Avoid concomitant use of GIVLAARI with CYP1A2 or CYP2D6 substrates for which minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP1A2 or CYP2D6 substrate dosage in accordance with approved product labeling.

Adverse Reactions

The most common adverse reactions that occurred in patients receiving GIVLAARI were nausea (27%) and injection site reactions (25%).

For additional information about GIVLAARI, please see full Prescribing Information.

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Alnylam® PHARMACEUTICALS

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