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

Start Form

Alnylam ASSIST®

▷ Before submitting the Start Form to Alnylam Assist®, patient **and** prescriber signatures are required

For Patients

Alnylam Assist® Enrollment

(Sections 1 – 5 to be read and completed by **Patient** or **Patient's Authorized Representative**)

The purpose of this form is to permit Alnylam Assist® participants to receive information and support ("Patient Support") from Alnylam Pharmaceuticals, Inc., its affiliates, representatives, agents, and contractors ("Alnylam"). Alnylam Assist® provides Patient Support to eligible patients who have been prescribed an Alnylam medicine. This includes: (1) providing reimbursement and financial support (such as investigating your insurance coverage, confirming out-of-pocket costs, and reviewing eligibility for financial assistance); (2) working with you and your provider to fill your prescription; and (3) providing you with disease and medication-related communications.

Please read this form carefully and ask any questions that you may have before signing.

1. Patient Information

Name (First, MI, Last):			Gender: ☐ Male ☐ Female
Date of Birth: Month/Day/Year	Email:		
Street Address:			
City:	State:	ZIP:	
Preferred Phone Number: ☐ **Okay to leave voicemail**	Alternative Phone Number (if different from preferred): ☐ **Okay to leave voicemail**		
Caregiver Name (optional):	Caregiver Relationship to Patient (optional):	Caregiver Phone (optional):	

Language translation? ☐ Yes, translation needed ☐ No If yes, please indicate language:

2. Insurance Information

Attach a copy of both sides of your INSURANCE and PRESCRIPTION cards ☐ Check if you do not have insurance

Primary Insurance Provider:	Employer Name:	Policy Number:		Group Number:
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth: Month/Day/Year		Insurance Phone:
Pharmacy Plan Provider (if applicable):	Policy Number:	Group Number:	Rx BIN Number:	Rx PCN Number:
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth: Month/Day/Year		Insurance Phone:
Secondary Insurance Provider (if applicable):	Employer Name:	Policy Number:		Group Number:
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth: Month/Day/Year		Insurance Phone:

▷ Continue to page 2 to complete the patient portion of the Start Form

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

3. Authorization to Share Protected Health Information

By signing below, I authorize my healthcare providers, including my physicians and pharmacies ("My Providers") and my health insurance plan ("My Plan") to share my medical information (such as information about my diagnosis, prescriptions, and treatment) and my insurance information ("My Information") with Alnylam so that Alnylam can provide Patient Support. I authorize My Providers to use My Information to provide me with certain offerings related to my medication and treatment. I understand that my pharmacy will receive payment from Alnylam for disclosing My Information to Alnylam. I understand that once My Information has been disclosed, federal privacy laws may no longer protect the information. However, I understand that Alnylam agrees to protect My Information by using and disclosing it only for purposes described in this Authorization or as required by law or regulations. I understand that I may refuse to sign this Authorization, and that my treatment, insurance enrollment, and eligibility for insurance benefits are not conditioned upon signing this Authorization. I also understand, however, that refusing to sign this Authorization means that I may not participate in Alnylam Assist® and may not be able to take advantage of other offerings by Alnylam. I may cancel or revoke this Authorization at any time by mailing a letter to Privacy Officer at Alnylam, Attn: Legal Department, 675 West Kendall Street, Cambridge, MA 02142 or by sending an email to privacy@alnylam.com. I understand that if I revoke this Authorization, My Providers and Alnylam will stop using and sharing My Information under this Authorization, but my revocation will not affect uses and disclosures of My Information prior to my revocation in reliance upon this Authorization.

This Authorization expires ten (10) years from the date signed below, or earlier if required by state or local law, unless I revoke it before then. I understand that I may receive a copy of this Authorization.

Print Patient or Authorized Patient Representative Name	X Signature of Patient or Authorized Patient Representative
Relationship to Patient	Date

4. Authorization for Alnylam Assist® and Communications

By signing below, I confirm I would like to enroll in the Alnylam Assist® program and authorize Alnylam to provide me with Alnylam Assist®. I understand that Alnylam Assist® is an optional program.

I agree that Alnylam may use My Information and share it with My Providers or My Plan in connection with providing the Patient Support, administering the Alnylam Assist® program, or as otherwise required by Alnylam to meet its legal obligations. For example, Alnylam may communicate with me (such as by mail, phone, email, and/or text message) or my caregiver, use My Information to tailor the Alnylam Assist®-related communications to my needs, and share information with My Providers about dispensing my Alnylam medicine to me. I understand that Alnylam may de-identify My Information, combine it with information about other patients, and use the resulting information for Alnylam's business purposes.

Print Patient or Authorized Patient Representative Name	X Signature of Patient or Authorized Patient Representative
Relationship to Patient	Date

5. Opt In to Receive Marketing Communications (optional)

Alnylam would like to contact you regarding Alnylam's medicines or Alnylam information that may be of interest to you.

Email (if not included above) _____

☐ By checking this box, I authorize Alnylam, and companies working with Alnylam, to contact me by mail, email, fax, and/or telephone regarding other potential topics of interest to me, surveys, or occasionally for market research purposes. **I understand that I am not required to provide this consent as a condition of receiving any Alnylam medicine or services from Alnylam.**

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

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For Healthcare Providers

(Sections 6 – 8 to be read and completed by **Healthcare Provider**)

6. Prescriber Information

Name (First, Last):			Practice Name:	Specialty:
Practice Street Address:			City:	State:
ZIP:	Phone:	Fax:	National Provider ID (NPI) #:	State License #:
Office Contact Name:			Phone:	Email:

Product acquisition:

- ☐ Specialty Pharmacy:
  - ○ Accredo ○ PANTHERx ○ No preference
- ☐ Specialty Distributor (McKesson Specialty Health)
- ☐ Unknown

Anticipated First Treatment Date:

7. GIVLAARI™(givosiran) Prescription (This is a prescription; a prescriber's signature and date are required.)

Patient Name:	Date of Birth: Month/Day/Year:

☐ I confirm that my patient is being prescribed GIVLAARI for the treatment of acute hepatic porphyria (AHP) in adults.

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

GIVLAARI Injection for subcutaneous use, 189 mg/mL (Recommended dose is 2.5 mg/kg monthly)	Date Patient Weight Taken	Patient Weight (in kg)	Total Calculated Dose (SC monthly)	Number of Vials Needed	Refills
			(mg) _____ (mL) _____	_____ 189 mg/mL vial(s)	☐ Refill x 11 ☐ Other _____

Any known allergies? ☐ Yes ☐ No

If yes, please list: _____

List or attach a list of concomitant medications:

Special Instructions:

☐ If acquiring through Accredo or PANTHERx, please check here to authorize ancillary supplies, such as needles and syringes, as needed to administer treatment.

X	
Prescriber Signature (No Stamps) Dispense as Written	Date
X	
Prescriber Signature (No Stamps) Substitution Permitted	Date

Desired Site of Care

- ☐ Home Injection (see patient home address)
- ☐ Alternate Medical Facility (provide facility name and address)
- ☐ Physician Office (see provider office address)
- ☐ Facility to Home (first dose at facility; remainder at home)

Facility Name/Address _____

I authorize Alnylam to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan. I will comply with my state-specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc.

▷ Continue to page 4 to complete the prescriber portion of the Start Form

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

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8. Prescriber Declaration

By signing below, I certify that:

- ▷ The information contained in this form is complete and accurate to the best of my knowledge
- ▷ I understand that Alnylam is not responsible for filing claims or submitting other information to my patient's insurer and that the information provided by Alnylam Assist® is advisory in nature
- ▷ I understand that my patient may authorize Alnylam Assist® to provide Patient Support. I understand that this program does not include individual treatment or medical advice to the patient, and it does not replace the medical treatment and care provided by me as the patient's healthcare provider. I further certify that I understand that any service provided by Alnylam Assist® on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use GIVLAARI™ (givosiran) or any other Alnylam product, and any decision to prescribe GIVLAARI was, and in the future will be, based solely on my determination of medical necessity
- ▷ I have obtained the required authorizations from my patient to release the referenced medical and/or other patient information relating to my patient's treatment to Alnylam Assist®

x _____ _____

Prescriber signature (stamps not acceptable) Date

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.

Fax the completed Start Form to 1-833-256-2747 | Call Alnylam Assist® at 1-833-256-2748 8AM–6PM ET, Monday–Friday | For more information, visit www.AlnylamAssist.com

Alnylam® PHARMACEUTICALS

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