Alnylam ASSIST®

How to Complete the GIVLAARI® (givosiran) Start Form

Please see Important Safety Information on page 7 and full Prescribing Information.

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

How to Complete the GIVLAARI® (givosiran) Start Form

This brochure will show you how to complete the Start Form. The notes on each page provide details to help ensure the form is filled out correctly. The Start Form serves as your patient's enrollment in Alnylam Assist® and requires the signature of both you and your patient. The Start Form also initiates your patient's prescription for GIVLAARI.

It is important to note the following before submitting the Start Form:

- Ensure highlighted key areas are correctly filled out
- Confirm that you and your patient sign where indicated

Options for getting started

1. Complete and submit the **electronic Start Form** with your patient **or**
2. Complete the **paper Start Form** with your patient and fax to 1-833-256-2747 **or**
3. Begin the Start Form, filling in all details needed by a healthcare professional, and then have your patient complete the form via **DocuSign**

All 3 options to get started can be found at **www.AlnylamAssist.com**.

Please see Important Safety Information on page 7 and full Prescribing Information.

Alnylam ASSIST®

For Patients

Your Patient's Email

Please make sure your patients fill in this field.

Preferred Phone Number & Voicemail Checkbox

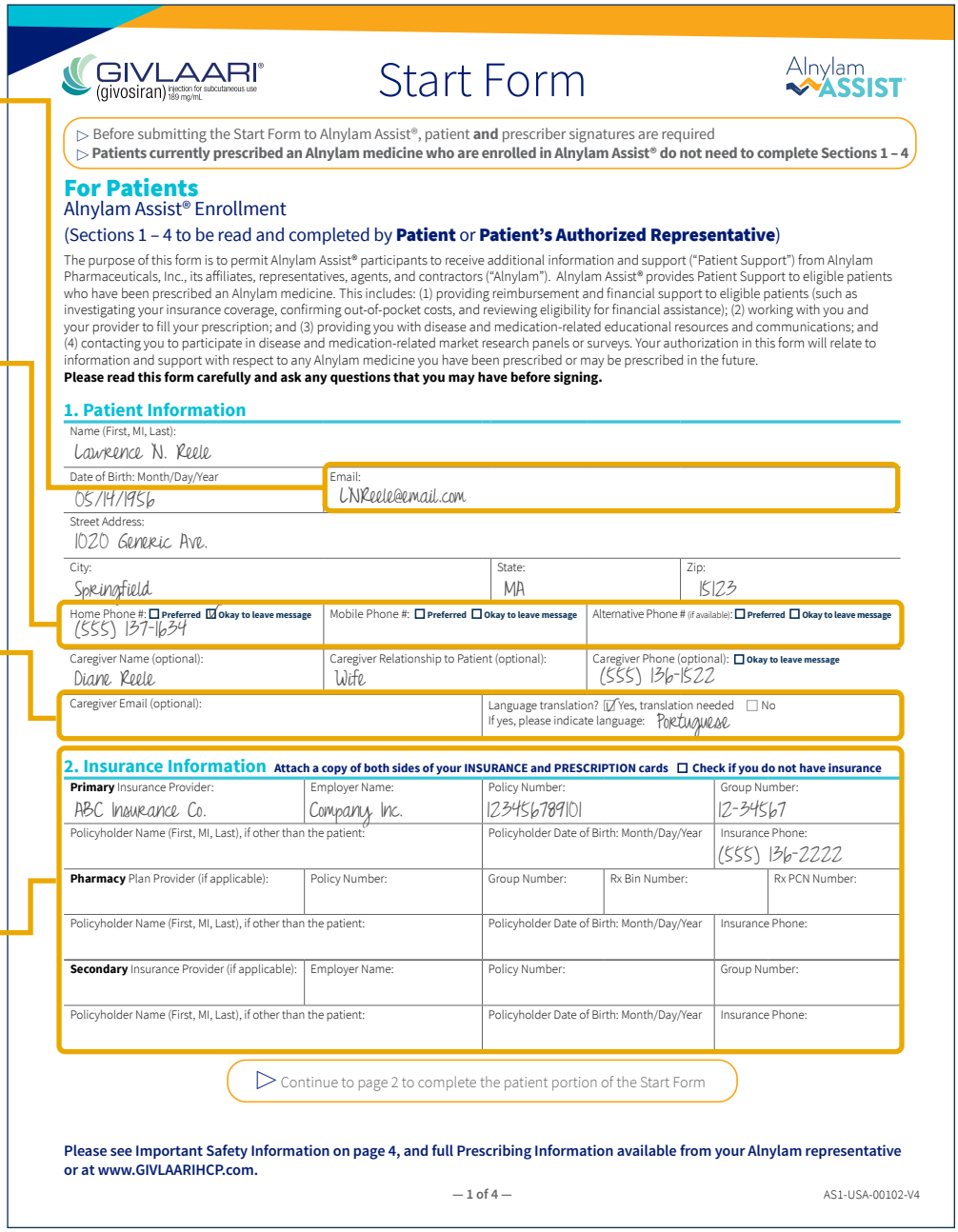
By allowing Alnylam Assist® to leave voicemails, delays in benefit verification and other communications can be avoided.

Language Translation

Alnylam Assist® offers translation services for non–English-speaking patients.

Insurance Information

Patients (or their authorized representatives) can fill in the provided fields or attach copies of both sides of their insurance and pharmacy benefits cards.



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
▷ **Patients currently prescribed an Alnylam medicine who are enrolled in Alnylam Assist® do not need to complete Sections 1 – 4**

For Patients
Alnylam Assist® Enrollment
(Sections 1 – 4 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 additional 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 to eligible patients (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 educational resources and communications; and (4) contacting you to participate in disease and medication-related market research panels or surveys. Your authorization in this form will relate to information and support with respect to any Alnylam medicine you have been prescribed or may be prescribed in the future.
Please read this form carefully and ask any questions that you may have before signing.

1. Patient Information

Name (First, MI, Last): Lawrence N. Reele		
Date of Birth: Month/Day/Year 05/14/1956	Email: LNReele@email.com	
Street Address: 1020 Generic Ave.		
City: Springfield	State: MA	Zip: 15123
Home Phone #: ☐ Preferred ☑ Okay to leave message (555) 137-1634	Mobile Phone #: ☐ Preferred ☐ Okay to leave message	Alternative Phone # (if available): ☐ Preferred ☐ Okay to leave message
Caregiver Name (optional): Diane Reele	Caregiver Relationship to Patient (optional): Wife	Caregiver Phone (optional): ☐ Okay to leave message (555) 136-1522
Caregiver Email (optional):	Language translation? ☑ Yes, translation needed ☐ No If yes, please indicate language: Portuguese	

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: ABC Insurance Co.	Employer Name: Company Inc.	Policy Number: 12345678910l	Group Number: 12-34567
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth: Month/Day/Year	Insurance Phone: (555) 136-2222
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 available from your Alnylam representative or at www.GIVLAARIHCP.com.

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AS1-USA-00102-V4

Please see Important Safety Information on page 7 and full Prescribing Information.

Authorization to Share Protected Health Information/ Authorization for Alnylam Assist® Enrollment

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

Start Form

Alnylam ASSIST®

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 treatment and any Alnylam medicine My Providers may prescribe for me at any time. 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. 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.

For information about how your personal data is processed as a part of our program, please visit https://alnylampolicies.com/privacy.

Lawrence N. Reele	X [signature]
Print Patient or Authorized Patient Representative Name	Signature of Patient or Authorized Patient Representative
	January 1, 2023
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 Patient Support. 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, request feedback or participation in market research, and share information with My Providers about dispensing 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.

Lawrence N. Reele	X [signature]
Print Patient or Authorized Patient Representative Name	Signature of Patient or Authorized Patient Representative
	January 1, 2023
Relationship to Patient	Date

Please see Important Safety Information on page 4, and full Prescribing Information available from your Alnylam representative or at www.GIVLAARIHCP.com.

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Signature of Patient

The signature of the patient or authorized patient representative, with the date, is required **twice** on this page in Sections 3 and 4.

Please see Important Safety Information on page 7 and full Prescribing Information.

Alnylam ASSIST®

For Healthcare Providers

Product Acquisition

Select your preferred method of product acquisition (specialty pharmacy or specialty distributor). If acquisition method is unknown, select *Unknown*.

GIVLAARI® (givosiran) Dosing Information

- Confirm that your patient is being prescribed GIVLAARI as indicated by **checking the box**
- Make sure to include the **primary diagnosis code** and **patient's weight (kg)**

GIVLAARI Prescription

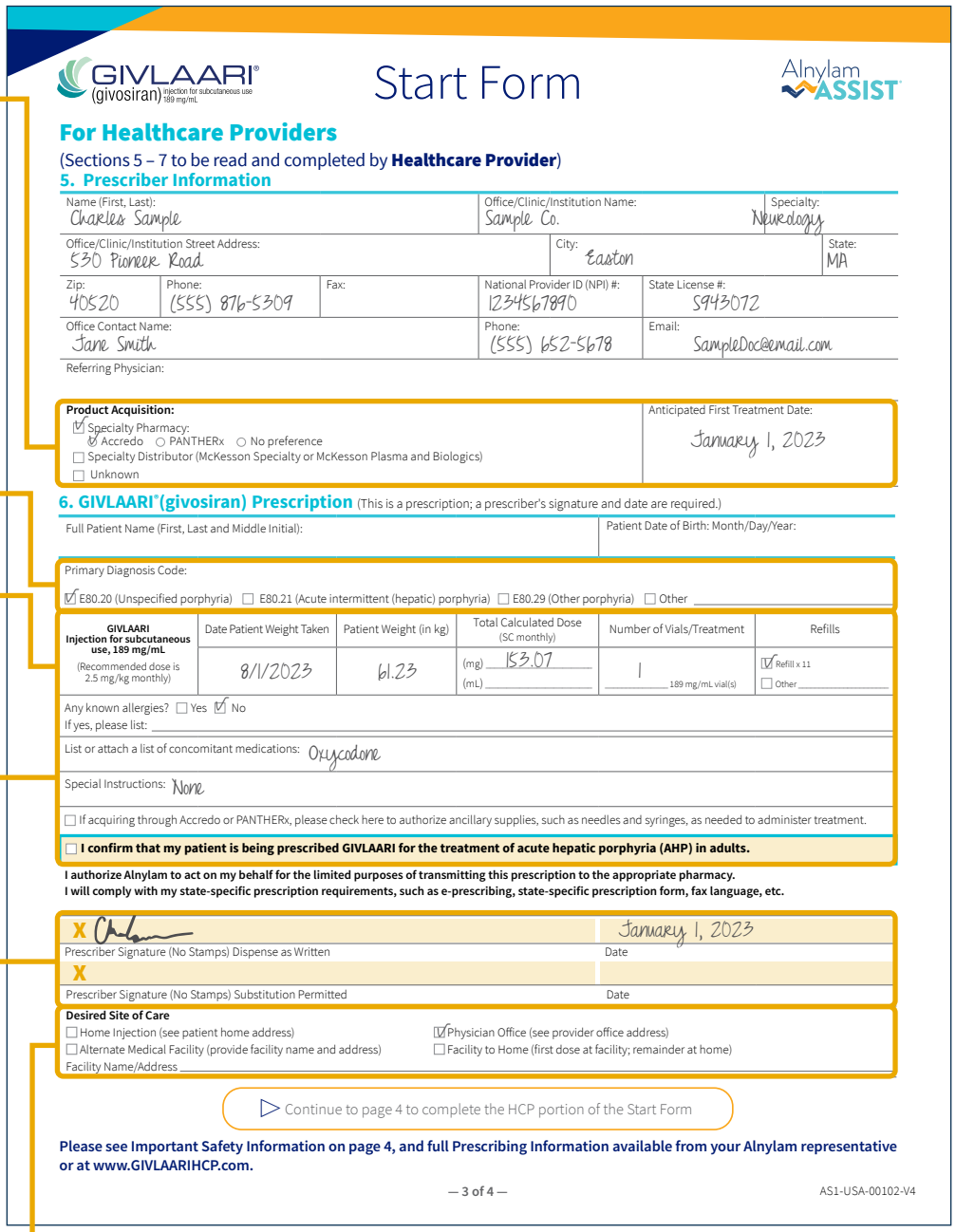
Ensure you fill in this prescription field for your patients.

Signature of Prescriber

Prescriber should only sign one prescription field and include date in Section 6.

To prevent a generic substitution, sign the "dispense as written" field.

To allow generic substitutions, sign the "substitution permitted" field.



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

Start Form

Alnylam ASSIST

For Healthcare Providers

(Sections 5 – 7 to be read and completed by **Healthcare Provider**)

5. Prescriber Information

Name (First, Last):	Office/Clinic/Institution Name:	Specialty:
Charles Sample	Sample Co.	Neurology

Office/Clinic/Institution Street Address:	City:	State:
530 Pioneer Road	Easton	MA

Zip:	Phone:	Fax:	National Provider ID (NPI) #:	State License #:
40520	(555) 876-5309		1234567890	S943072

Office Contact Name:	Phone:	Email:
Jane Smith	(555) 652-5678	SampleDoc@email.com

Referring Physician:

Product Acquisition:
☑ Specialty Pharmacy:
◉ Accredo ○ PANTHERx ○ No preference
☐ Specialty Distributor (McKesson Specialty or McKesson Plasma and Biologics)
☐ Unknown

Anticipated First Treatment Date: January 1, 2023

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

Full Patient Name (First, Last and Middle Initial):

Patient Date of Birth: Month/Day/Year:

Primary Diagnosis Code:
☑ 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/Treatment	Refills
	8/1/2023	61.23	(mg) 153.07 (mL)	1 189 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: Oxycodone

Special Instructions: None

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

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

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

X [signature] — January 1, 2023
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)
☑ Physician Office (see provider office address)
☐ Alternate Medical Facility (provide facility name and address)
☐ Facility to Home (first dose at facility; remainder at home)
Facility Name/Address

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

Please see Important Safety Information on page 4, and full Prescribing Information available from your Alnylam representative or at www.GIVLAARIHCP.com.

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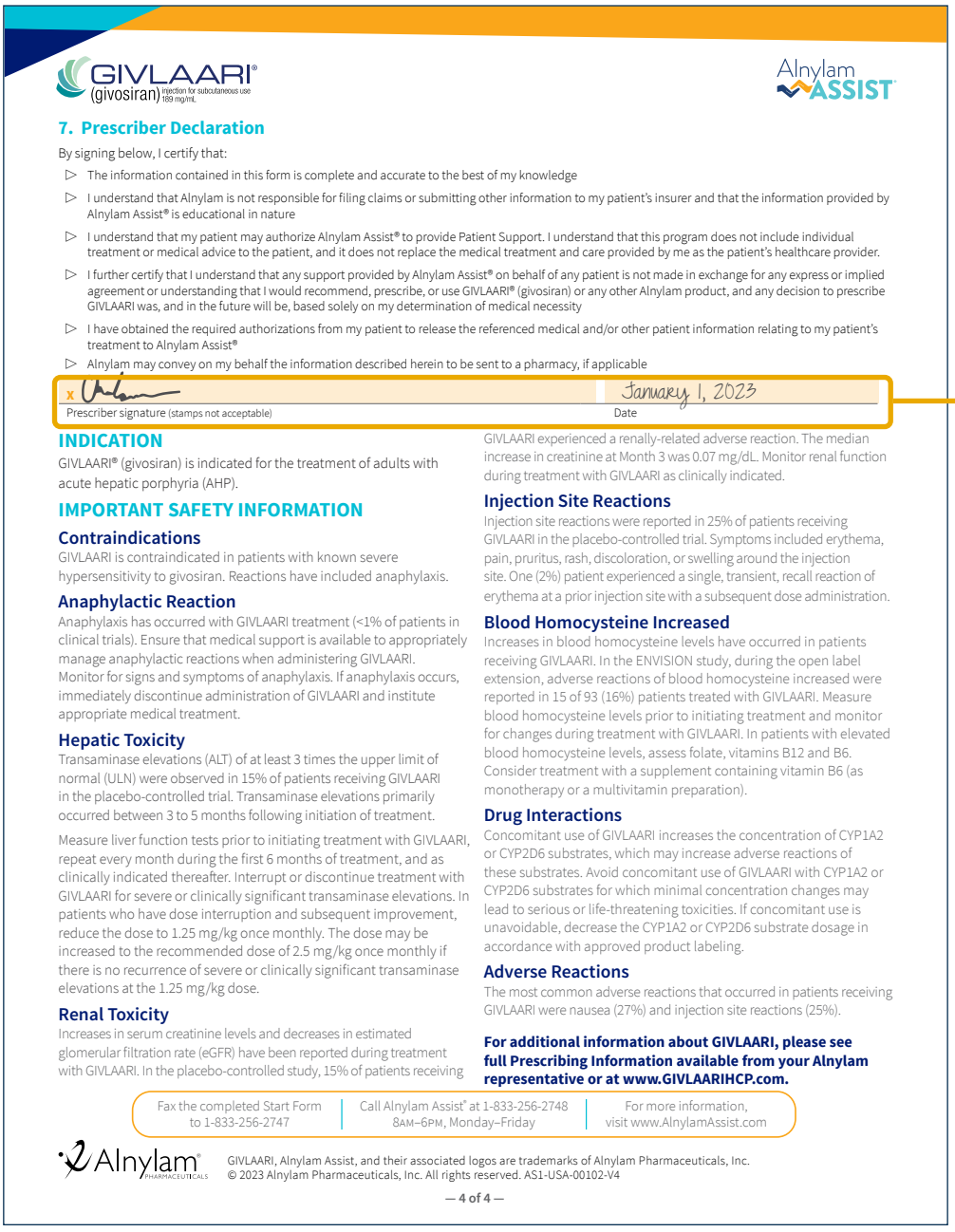
Desired Site of Care

Ask your patient where he or she would like to receive treatment.

Please see Important Safety Information on page 7 and full Prescribing Information.

Prescriber Declaration



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

Alnylam ASSIST

7. 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 educational 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 support 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®
- Alnylam may convey on my behalf the information described herein to be sent to a pharmacy, if applicable

x _____ January 1, 2023

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.

Blood Homocysteine Increased

Increases in blood homocysteine levels have occurred in patients receiving GIVLAARI. In the ENVISION study, during the open label extension, adverse reactions of blood homocysteine increased were reported in 15 of 93 (16%) patients treated with GIVLAARI. Measure blood homocysteine levels prior to initiating treatment and monitor for changes during treatment with GIVLAARI. In patients with elevated blood homocysteine levels, assess folate, vitamins B12 and B6. Consider treatment with a supplement containing vitamin B6 (as monotherapy or a multivitamin preparation).

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 available from your Alnylam representative or at www.GIVLAARIHCP.com.

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

Alnylam® PHARMACEUTICALS

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Signature of Prescriber

Sign and date the declaration on the last page, certifying the information provided in the form and authorization of services. Before submitting the form, ensure **both prescriber signatures** are provided in Sections 6 and 7.

Please see Important Safety Information on page 7 and full Prescribing Information.

Alnylam ASSIST®

INDICATION

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

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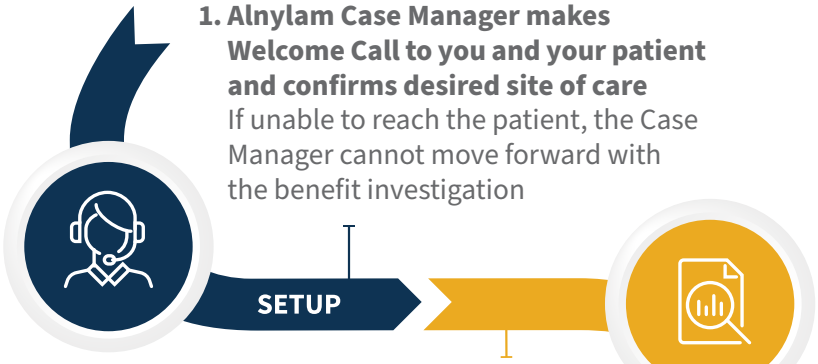
Adverse Reactions

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.

Once the Completed Start Form Is Received by Alnylam Assist®



1. Alnylam Case Manager makes Welcome Call to you and your patient and confirms desired site of care
If unable to reach the patient, the Case Manager cannot move forward with the benefit investigation

SETUP

2. Alnylam Case Manager does benefit investigation
If a patient's insurance or site of care changes, a new benefit investigation must be done

3. Alnylam Case Manager relays results of benefit investigation to you and your patient during "Benefits Call Counsel"
This includes information about prior authorization (if required)

BENEFIT INVESTIGATION

IF REQUIRED

Prescribing physician submits prior authorization

- It is the responsibility of the prescribing physician to submit the required documentation
- If the prior authorization is not approved, a resubmission or appeal may be required by the prescriber

Prior authorization is approved[a,b]

4. Alnylam Case Manager confirms copay affordability and site of care

5. Patient is "order ready"

TREATMENT[c]

6. Physician places order through specialty pharmacy or specialty distributor

Patient receives GIVLAARI® (givosiran) injection

by healthcare professional and schedules next dose of treatment

[a]If a reauthorization is required, a new request must be submitted.
[b]Alnylam Assist® can provide education on prior authorization requirements and processes, but cannot guarantee that a patient's prior authorization will be approved.
[c]If your patient has a new prescribing physician, a new Start Form is required and the process must be repeated.

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

Alnylam® PHARMACEUTICALS

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Alnylam ASSIST®

8 AM–6 PM, Monday–Friday

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