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

ACCESS & REIMBURSEMENT

Please see Important Safety Information on page 3 and full Prescribing Information.

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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).

Pancreatitis

Cases of acute pancreatitis, some severe, have been reported in patients receiving GIVLAARI. To ensure appropriate management, consider acute pancreatitis as a potential diagnosis in patients with signs/symptoms of acute pancreatitis. Consider interruption and/or discontinuation of GIVLAARI treatment for severe cases.

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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Billing and Coding Overview

Please see Important Safety Information on page 3 and full Prescribing Information.

Coverage, coding, and payment

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

Coverage

- **For Medicare patients** receiving GIVLAARI who are covered under Medicare Part B, the Medicare Administrative Contractors (MACs) may require additional documentation to determine the medical necessity of the treatment, although prior authorization is not required[a,b]
- **For patients enrolled in a State Medicaid or commercial health plan**, GIVLAARI coverage will vary by payer

Payment

Payer Type	Payment Methodology
Medicare Fee-for-Service	Average Sales Price (ASP) + 6%[c]
State Medicaid and Commercial Payers	Payment rates will vary by payer and provider contract

[a]It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.
[b]Medicare Advantage Plans may require a prior authorization for GIVLAARI.
[c]Does not account for any required payment reductions if sequestration is in effect.

Alnylam **Field Reimbursement Directors** are available to meet with you and your staff to answer coverage, coding and reimbursement questions about GIVLAARI. Contact Alnylam Assist® at 1-833-256-2748.

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Billing and Coding

Physician Office

Please see Important Safety Information on page 3 and full Prescribing Information.

Coding[a]

Please refer to the table below to support appropriate claims submission for GIVLAARI® (givosiran).

Code Type	Code	Code Description
ICD-10-CM	E80.20 E80.21 E80.29	Unspecified porphyria Acute intermittent (hepatic) porphyria Other porphyria
CPT®[b]	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
HCPCS	J0223	Injection, givosiran, 0.5 mg
NDC	10-digit: 71336-1001-1 11-digit: 71336-1001-01	189 mg/mL single-dose vial

[a]It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for products and services rendered. Providers should contact payers for specific information on their coding, coverage, and payment policies.

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Applicable FARS/DFARS Restrictions Apply to Government Use.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

Providers should consult the ICD-10-CM code book and use their own clinical judgment to confirm coding.

Please see Important Safety Information on page 3 and full Prescribing Information.

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Physician office: sample CMS-1500 claim form

GIVLAARI® (givosiran) and the associated services provided in a physician office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing GIVLAARI is provided on the next page.

- The following CMS-1500 claim form for GIVLAARI is for illustrative purposes
- It is the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered
- Providers should contact payers for specific information on their coding, coverage, and payment policies
- Payers may limit the charges on a single claim, rejecting claims over the specified limit. Providers should contact payers for information on claim charge limits and claims submission guidance
- Medicare claims require the use of the JW (drug amount discarded/not administered to any patient) or JZ (zero drug amount discarded/not administered to any patient) modifiers when applicable
  - Effective for dates of service on or after January 1, 2017, Medicare requires the use of the JW modifier on any claims for single-use vials when there is discarded drug
  - Effective for dates of service on or after July 1, 2023, Medicare requires the use of the new JZ modifier on any claims for single-use vials when there are no discarded drug amount
  - Wastage-reporting policies for payers other than Medicare may vary. Providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifier
- Providers should contact their billing software vendors to ensure that they are utilizing the recommended loops and segments

Dosing calculation example

- GIVLAARI is supplied as a 189 mg/mL solution in a single-dose vial
- The recommended dose of GIVLAARI is 2.5 mg/kg administered via subcutaneous injection once monthly
- Dosing is based on actual body weight

Calculation

How to Calculate Dosage (mg)	How to Calculate Injection Volume (mL)
(body weight [kg] x 2.5 mg/kg) = mg	(mg x 1 mL/189 mg) = mL

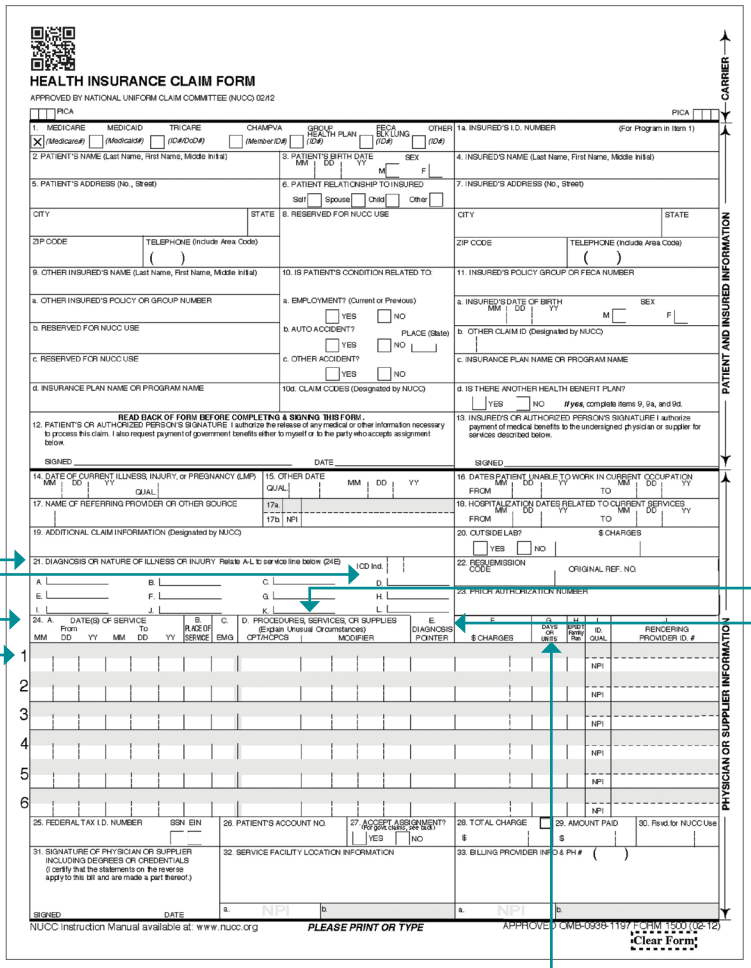
Example - 68 kg patient

Dosage (mg)	Injection Volume (mL)
68 kg x 2.5 mg/kg = 170 mg	170 mg x 1 mL/189 mg = 0.9 mL

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Sample CMS-1500 Claim Form



LOCATOR
21
Enter the appropriate primary diagnosis code from the patient's medical record in Locator 21A.

LOCATOR
21 ICD-IND
Enter "0" to indicate use of ICD-10-CM diagnosis coding system.

LOCATOR
24A-B
Enter the date of service and the appropriate place of service code.

LOCATOR
24
Enter the GIVLAARI® (givosiran) HCPCS code J0223 on the first line and the CPT code 96372 for drug administration on the second line.

LOCATOR
24D
Enter the appropriate HCPCS code for GIVLAARI: J0223 (injection, givosiran, 0.5 mg).

Shaded area of Locator 24D (when applicable): N4713613610001O1 MLX (X = number of ML; for example, ML1 = 1 vial, ML2 = 2 vials, etc.)

LOCATOR
24E
Specify the diagnosis, from Locator 21, that relates to the product or procedure listed in Locator 24D.

LOCATOR
24G
Enter the number of service units for each line item.

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Clean claim filing checklist

- **Select the appropriate primary diagnosis**
- **Confirm appropriate clinical documentation to support diagnosis**
- **Understand any payer-specific requirements (prior authorization, coding details, etc)**
- **Utilize all appropriate ICD-10, CPT®, and HCPCS codes**
  - For all claims in the physician office setting, use HCPCS J0223 (Injection, givosiran, 0.5 mg)[a]
    - Remember: Billing Unit = 0.5 mg
  - Remember to use the sample claim form on page 25 as a guide
- **Anticipate requests from payers for additional clinical information prior to claims being processed for payment**

It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for those products and services rendered. Contact third-party payers for specific information on their coding and payment policies.

[a]HCPCS codes for GIVLAARI® (givosiran) may vary for dates of service prior to July 1, 2020.

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Billing and Coding

Hospital Outpatient Department

Please see Important Safety Information on page 3 and full Prescribing Information.

Coding[a]

Please refer to the table below to support appropriate claims submission for GIVLAARI® (givosiran).

Code Type	Code	Code Description
ICD-10-CM	E80.20 E80.21 E80.29	Unspecified porphyria Acute intermittent (hepatic) porphyria Other porphyria
CPT®[b]	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
HCPCS	J0223	Injection, givosiran, 0.5 mg
Revenue	0250	General pharmacy
	0940	Other therapeutic services
	0636	Drugs requiring detailed coding
NDC	10-digit: 71336-1001-1 11-digit: 71336-1001-01	189 mg/mL single-dose vial

[a]It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for products and services rendered. Providers should contact payers for specific information on their coding, coverage, and payment policies.

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ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

Providers should consult the ICD-10-CM code book and use their own clinical judgment to confirm coding.

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Hospital outpatient: sample UB-04 claim form

GIVLAARI® (givosiran) and the associated services provided in a hospital outpatient department setting are billed on the UB-04 claim form or its electronic equivalent. A sample UB-04 claim form for billing GIVLAARI is provided on the next page.

- The following UB-04 claim form for GIVLAARI is for illustrative purposes
- It is the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered
- Providers should contact payers for specific information on their coding, coverage, and payment policies
- Payers may limit the charges on a single claim, rejecting claims over the specified limit. Providers should contact payers for information on claim charge limits and claims submission guidance
- Medicare claims require the use of the JW (drug amount discarded/not administered to any patient) or JZ (zero drug amount discarded/not administered to any patient) modifiers when applicable
  - Effective for dates of service on or after January 1, 2017, Medicare requires the use of the JW modifier on any claims for single-use vials when there is discarded drug
  - Effective for dates of service on or after July 1, 2023, Medicare requires the use of the new JZ modifier on any claims for single-use vials when there are no discarded drug amount
  - Wastage-reporting policies for payers other than Medicare may vary. Providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifier
- Providers should contact their billing software vendors to ensure they are utilizing the recommended loops and segments

Dosing calculation example

- GIVLAARI is supplied as a 189 mg/mL solution in a single-dose vial
- The recommended dose of GIVLAARI is 2.5 mg/kg administered via subcutaneous injection once monthly
- Dosing is based on actual body weight

Calculation

How to calculate Dosage (mg)	How to calculate Injection Volume (mL)
(body weight [kg] x 2.5 mg/kg) = mg	(mg x 1 mL/189 mg) = mL

Example - 68 kg patient

Dosage (mg)	Injection Volume (mL)
68 kg x 2.5 mg/kg = 170 mg	170 mg x 1 mL/189 mg = 0.9 mL

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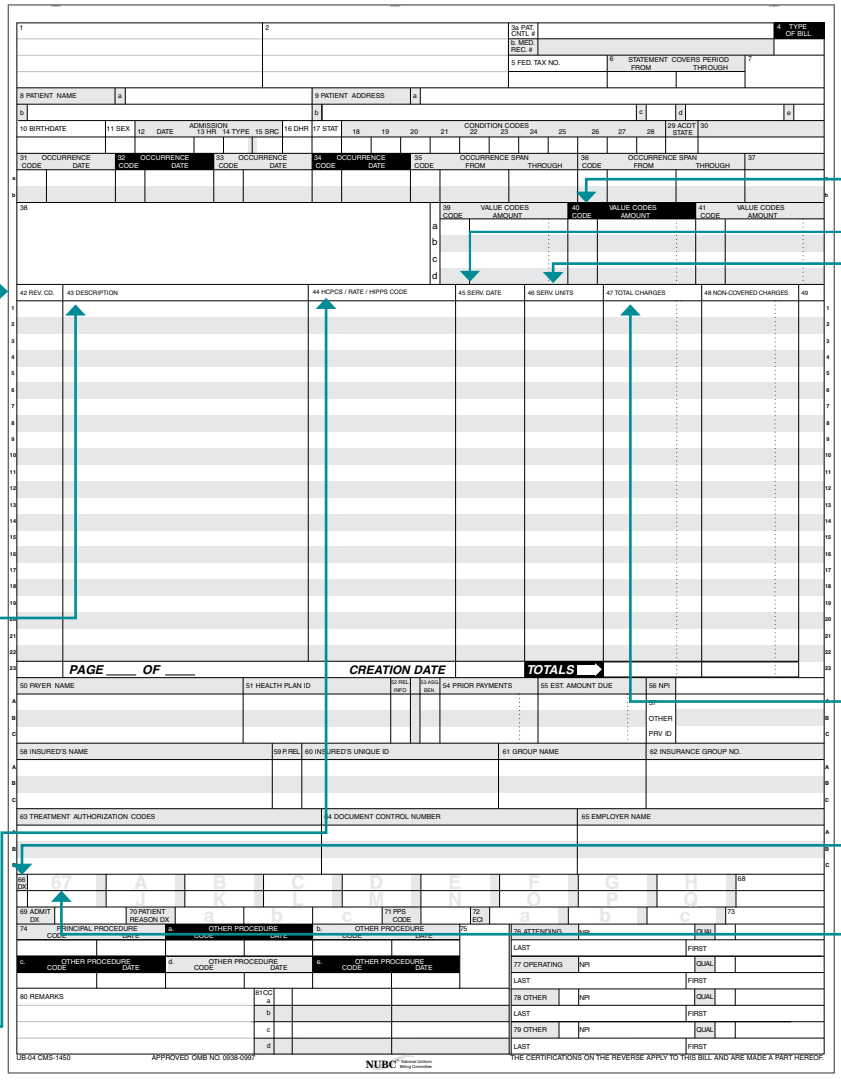
Sample UB-04 Claim Form



LOCATOR
42
List the appropriate revenue code for the service provided.

For Medicare, use the revenue code 0636—Drugs requiring detailed coding.

For payers other than Medicare, the revenue code for GIVLAARI may vary, although some private payers and **Medicaid** plans accept revenue code 0250—General pharmacy.

LOCATOR
43
Enter the corresponding description for the revenue code listed in Locator 42 **OR** Enter the NDC (when applicable): N471336100301 MLX (X = number of ML; for example, ML1 = 1 vial, ML2 = 2 vials, etc.)

LOCATOR
44
Enter the appropriate HCPCS code for GIVLAARI: J0223 (injection, givosiran, 0.5 mg).

LOCATOR 40
Enter the GIVLAARI® (givosiran) HCPCS code J0223 on the first line and the CPT code 96372 for drug administration on the second line.

LOCATOR 45
Enter the service date.

LOCATOR 46
Enter the number of service units for each line item.

LOCATOR 47
Enter the total charge for each line item.

LOCATOR 66
Enter "0" to indicate use of the ICD-10-CM diagnosis coding system.

LOCATOR 67
Enter the primary diagnosis code.

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Clean claim filing checklist

- **Select the appropriate primary diagnosis**
- **Confirm appropriate clinical documentation to support diagnosis**
- **Understand any payer-specific requirements (prior authorization, coding details, etc)**
- **Utilize all appropriate ICD-10, CPT®, HCPCS, and Revenue codes**
  - For all claims in the hospital outpatient department setting, use HCPCS code J0223[a]
    - Remember: Billing Unit = 0.5 mg
  - Remember to use the sample claim form on page 30 as a guide
- **Anticipate requests from payers for additional clinical information prior to claims being processed for payment**

It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for those products and services rendered. Contact third-party payers for specific information on their coding and payment policies

[a]HCPCS codes for GIVLAARI® (givosiran) will vary for dates of service prior to July 1, 2020.

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Alnylam ASSIST®

Copay Claim Submission Guide

Please see Important Safety Information on page 3 and full Prescribing Information.

Copay claim submission

The following outline will show you how to submit a medical benefits claim, pharmacy claim, or a patient-submitted claim for GIVLAARI® (givosiran). Before submitting a claim, please ensure the following:

- The patient is enrolled in Alnylam Assist® (via the Start Form found at AlnylamAssist.com)
- The patient's benefits have been verified
- The patient has provided their medical benefit or pharmacy member number

Upon a patient's enrollment into the copay program, an Alnylam Case Manager will provide your practice with the patient's Payer ID, Group Number, and Member Number required to submit a copay claim.

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Submitting Copay Claims for GIVLAARI® (givosiran)

SUBMIT THE PRIMARY CLAIM TO THE PATIENT'S PRIMARY INSURANCE

MEDICAL BENEFITS CLAIMS

Receive a line level explanation of benefits (EOB) from the payer

Submit the secondary claim to UBC via fax or secure email[a]

Fax or email claim: Provider Copay Reimbursement Form, CMS 1500 or UB 04
Fax: 800-984-8816, email: AlnylamCopay@UBC.com

UBC will process the claim and send an Electronic Funds Transfer (EFT) or email a check with the payment

PATIENT-SUBMITTED CLAIMS[b]

Alnylam Case Manager sends reimbursement form upon request

Patient pays copay to provider

Patient submits reimbursement form along with claim documentation (pharmacy receipt, EOB, or billing statement) to UBC via fax, email, or mail

UBC will process the claim and email the patient a check with the payment

PHARMACY CLAIMS

Primary claim is submitted to the payer

Process a coordination of benefits (COB) claim

Claim and payment will be processed by the pharmacy claim adjudicator

For questions about claims submissions, please contact Customer Copay Support at 844-985-4498

[a]At Alnylam, we are committed to protecting privacy and encourage the utilization of secure email for submissions to safeguard sensitive patient information. Senders are asked to use secure email options for comprehensive data protection.

[b]Medical Benefits or Pharmacy Claims.

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Provider Readiness Guide

Please see Important Safety Information on page 3 and full Prescribing Information.

How Alnylam Assist® can help

Alnylam Assist® is dedicated to helping guide your patient through treatment with an Alnylam product.

Alnylam Assist® offers support services to help with:

- Securing access to an Alnylam product for your patient
- Initiating treatment for your patient
- Ordering product

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

Preparing for the coverage and reimbursement process

When prescribing an Alnylam product, please refer to the steps below.

With payers

1

Contact the payers through whom your patient has insurance coverage (commercial, local Medicare Administrative Contractor, State Medicaid, etc.) for additional information regarding appropriate coverage, coding, and payment policies.

- For example, discuss the payment methodology for the appropriate Healthcare Common Procedure Coding System (HCPCS) code with payers and what constitutes a clean claim

2

- Review the payer-specific coverage requirements and key medical necessity criteria

3

- Ensure accurate and proper chart documentation

With your practice

4

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 drug administration
- Ordering product for your patients
- Submitting claims to payers

The Alnylam Assist® team includes **Field Reimbursement Directors** who are knowledgeable in chart documentation best practices and billing and coding requirements for Alnylam products. They can answer your questions on these topics.

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5 Update charge master/electronic billing system to ensure that the Alnylam product is recognized.

6 Anticipate requests from payers for clinical documentation if filing a claim for an Alnylam product.

Initiating therapy

When preparing to treat a patient with an Alnylam product 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 enroll your patient in Alnylam Assist®.

- An Alnylam Case Manager will initiate verification of benefits and eligibility assessment for patient financial assistance, if appropriate.
- To access the Alnylam Assist® **Start Form**, visit **www.AlnylamAssist.com**

2 Schedule the patient for treatment.

3 Work with Alnylam Assist® to determine the method for ordering product.

- Alnylam Assist® will send your patient's prescription to a specialty pharmacy and/or provide you with details about a specialty distributor. For some patients, home administration may also be an option depending on their insurance coverage.

4 After treatment, complete and submit the claim to the payer, if appropriate.

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

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GIVLAARI® (givosiran) Clinical Documentation Considerations

Please see Important Safety Information on page 3 and full Prescribing Information.

Clinical Documentation Considerations

Payers may require documentation of medical necessity criteria, drug information, and other information to support prior authorization and coverage decision making for GIVLAARI® (givosiran). While payer coverage criteria vary by plan, below is a summary of select payer coverage requirements.

This information is provided as a guide to support payer interaction and reimbursement; however, the level of information required will vary based on key areas that the payer requires to be addressed to demonstrate medical necessity.

Note: Medical chart documentation should be based on each patient's individual history, prior testing results, clinical condition, and actions actually performed by the clinician and other parties.

Select Payer Coverage Criteria for Initiation of Treatment with GIVLAARI® (givosiran).

Clinical Criteria	Examples of Documentation Requirements
Diagnosis (acute hepatic porphyria type)	▪ Diagnosis of one of the following acute hepatic porphyria types: – Acute intermittent porphyria (AIP) – Variegate porphyria (VP) – Hereditary coproporphyria (HCP) – ALA dehydratase-deficiency porphyria (ADP)
Active disease	▪ Prior to starting treatment with GIVLAARI® (givosiran), a history of one porphyria attack in the last 6 months that required a hospitalization, urgent healthcare visit, or intravenous hemin administration at home ▪ At least 2 documented porphyria attacks within the past 6 months ▪ Currently receiving treatment with prophylactic hemin to prevent porphyria attacks*
Biomarkers	▪ Elevated urinary or plasma porphobilinogen (PBG) or delta-aminolevulinic acid (ALA) ▪ Elevated porphyrin level (plasma or fecal)
Clinical features	▪ Demonstrated clinical features associated with acute hepatic porphyria (e.g., neurovisceral symptoms, blistering lesions, hepatic involvement, peripheral neuropathy, abdominal pain, constipation, muscle weakness, pain in the arms and legs)
Prescriber specialty	▪ Medication is being prescribed by, or in consultation with, a gastroenterologist, hepatologist, medical geneticist or a physician who specializes in acute hepatic porphyria

*Some plans may also require that the patient will not receive concomitant prophylactic hemin treatment while on GIVLAARI

It is important to note that the information discussed in this guide is general in nature and does not capture all of the variation in coverage requirements across payers. Providers should always check with their Medicare contractor, state Medicaid program, and private payers to confirm coverage requirements.

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Alnylam ASSIST®

Support Services Overview

Alnylam Assist® offers support services to help your patients access Alnylam products

Please see Important Safety Information on page 3 and full Prescribing Information.

How Alnylam Assist® can help

After deciding to start your patient on treatment, begin the enrollment process by completing the Alnylam Assist® Start Form. Upon receipt of the Start Form, an Alnylam Case Manager will reach out to you and your patient within 2 business days.

Alnylam Assist® will help with:

- **Benefit verification**
- **Education on the prior authorizations, claims, and appeals processes**
- **Financial assistance program for eligible patients[a]**
- **Disease and product education**
- **Ordering product for your patient**

Alnylam Field Reimbursement Directors (FRDs) are also available to you to provide education about the coverage, coding, and reimbursement process for Alnylam products.

FRDs will share their knowledge of:

- Billing and coding requirements for Alnylam products
- Chart documentation requirements
- Payer requirements

[a] Patients must meet specified eligibility criteria to qualify for assistance. Alnylam reserves the right to make eligibility determinations and to modify or discontinue any program at any time.

Please see Important Safety Information on page 3 and full Prescribing Information.

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Support for patients throughout the treatment process

1 Complete Start Form

Electronic Start Form
Complete and submit the electronic Start Form online with your patient at www.AlnylamAssist.com

OR

Downloadable Start Form
Print, complete with your patient, and fax the Start Form to 1-833-256-2747

OR

DocuSign Start Form
Begin the Start Form and send to your patient by email to complete via DocuSign (link available at www.AlnylamAssist.com)

2 Alnylam Case Manager Reaches Out

3 Patient Assistance Offered

- Disease and product education
- Insurance
  - —Benefit verification and explanation
  - —Coverage, Coding, and Reimbursement education
- Financial assistance for eligible patients[a]

Visit www.AlnylamAssist.com to complete the Start Form with your patient now.

[a]Patients must meet specified eligibility criteria to qualify for assistance. Alnylam reserves the right to make eligibility determinations and to modify or discontinue any program at any time.

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Helping your patients access Alnylam products

Benefit verification

Coverage for Alnylam products will vary by product, by plan, and by patient. Alnylam Assist® can help determine patient-specific coverage requirements.

- After enrolling in Alnylam Assist®, an Alnylam Case Manager will initiate a benefit verification for your patient. To begin this process, complete the **Start Form** electronically or via DocuSign at www.AlnylamAssist.com. You can also download and print the Start Form and fax it to 1-833-256-2747

Questions about how Alnylam Assist® can help?
Call 1-833-256-2748

- Within 2 business days, an Alnylam Case Manager will provide you and your patient with a benefit verification summary
- Alnylam Assist® can provide information about patient financial assistance programs for eligible patients,[a] if necessary (for additional information on financial assistance programs, see page 30)

[a]Patients must meet specified eligibility criteria to qualify for assistance. Alnylam reserves the right to make eligibility determinations and to modify or discontinue any program at any time.

Please see Important Safety Information on page 3 and full Prescribing Information.

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Alnylam product coverage

Case Managers can explain the requirements and processes for prior authorizations, claims, and appeals.

Alnylam Assist® can:

- Research the payer requirements as part of the benefit verification process
- Discuss the standard process for submitting a prior authorization and reimbursement claims
- Investigate reasons for denied or rejected prior authorizations, claims, and/or appeals

Alnylam **Field Reimbursement Directors** are available to answer coverage, coding, and reimbursement-related questions about Alnylam products

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Support services for your patients

Alnylam Assist® can provide:

- An explanation of benefits so your patients understand their coverage
- Information about financial assistance programs for eligible patients[a]
- A Patient Starter Kit, including educational materials designed to help patients understand their therapy and Alnylam Assist®
- Education for patients from an **Alnylam Patient Education Liaison (PEL)**
  - Regionally based PELs are available to provide disease and product education and answer questions about treatment with one of Alnylam's products
  - PELs are employees of Alnylam Pharmaceuticals and do not provide medical advice
- Alnylam Case Managers will tailor their method of contact based on patient preference

[a]Patients must meet specified eligibility criteria to qualify for assistance. Alnylam reserves the right to make eligibility determinations and to modify or discontinue any program at any time.

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Financial assistance programs

Alnylam offers financial assistance programs for eligible patients. After being prescribed an Alnylam product, your patient can talk to an Alnylam Case Manager to learn more. Below are examples of two Alnylam financial assistance programs.[a]

- **Patient Assistance Program (PAP):** Provides Alnylam product at no cost to eligible patients, primarily the uninsured, who meet specified financial criteria
- **Commercial Copay Program:** Covers certain out-of-pocket costs for eligible patients with commercial insurance[b]

Eligibility criteria

PAP	Commercial Copay
Uninsured/functionally uninsured[c]	Commercially insured patients[b]
On-label diagnosis for prescribed Alnylam product	
US Citizen/Legal Permanent Resident	
Financial eligibility requirements—supporting income documentation required[d]	Insurance must cover the prescribed Alnylam product

Once enrolled in Alnylam Assist®, an Alnylam Case Manager will review assistance programs your patient may qualify for based on eligibility.

[a]Patients must meet specified eligibility criteria to qualify for assistance. Alnylam reserves the right to make eligibility determinations and to modify or discontinue any program at any time.
[b]Patients with Medicare, Medicaid, or other government-sponsored insurance are not eligible for the Alnylam Assist® Commercial Copay Program. Out-of-pocket costs for the administration of Alnylam products will not be covered for patients residing where it is prohibited by law or where otherwise restricted.
[c]Functionally uninsured patients are those who may be enrolled in a health plan but do not have coverage for an Alnylam product or cannot afford their cost share associated with their Alnylam product.
[d]Acceptable forms of documentation are: copy of most recent US Income Tax Return; most recent Social Security Income Statement; copy of most recent pay stub. Patients with an income of ≤150% FPL are required to apply for Limited Income Subsidy (LIS).

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Alnylam ASSIST®

How to Complete the GIVLAARI® (givosiran) Start Form

Please see Important Safety Information on page 3 and full Prescribing Information.

How to complete the GIVLAARI® (givosiran) Start Form

This section 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 signatures 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 3 and full Prescribing Information.

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

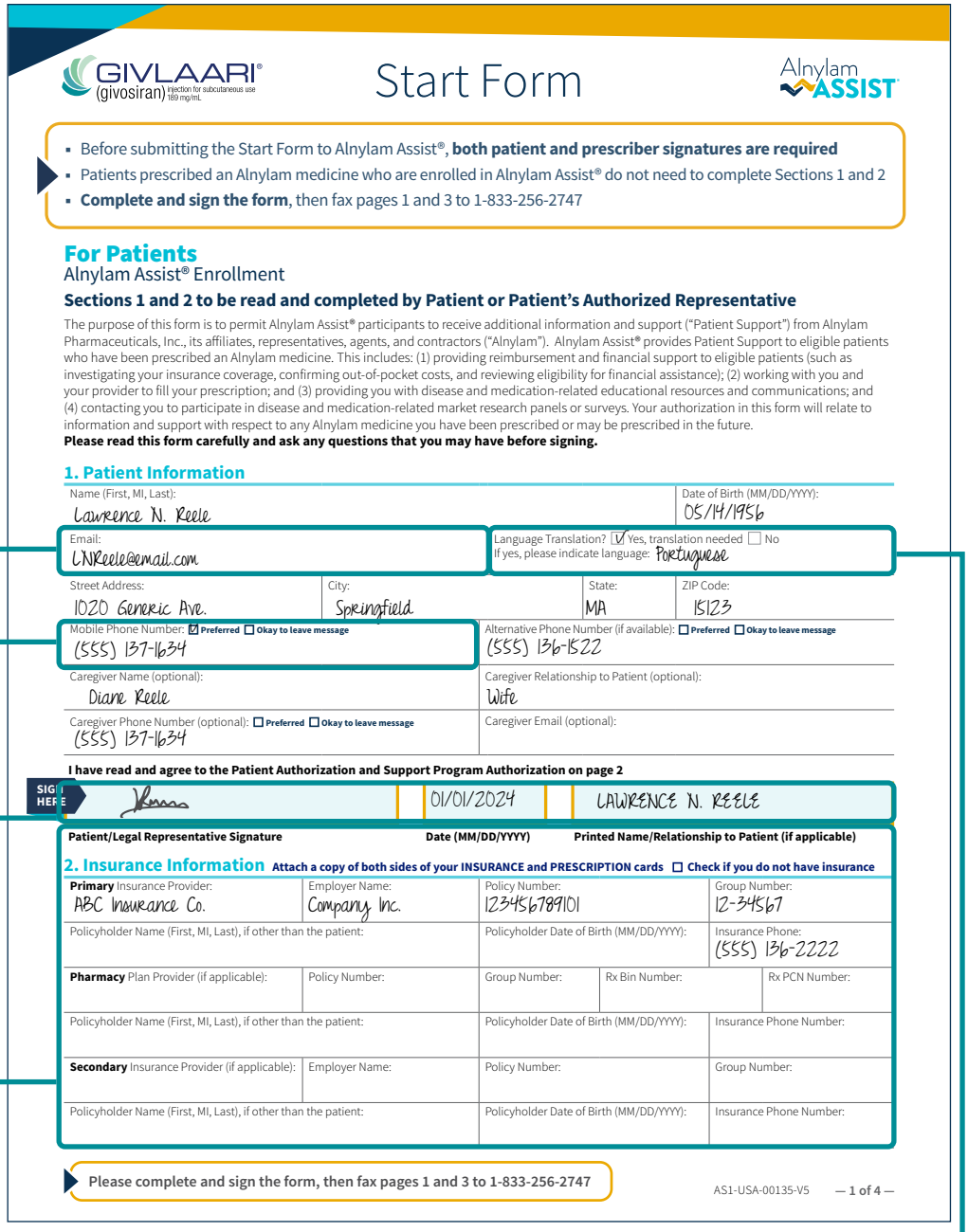
For patients

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.

Signature of Patient
The signature of the patient or authorized patient representative, with the date, is required on this page.

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®, **both patient and prescriber signatures are required**
- Patients prescribed an Alnylam medicine who are enrolled in Alnylam Assist® do not need to complete Sections 1 and 2
- **Complete and sign the form**, then fax pages 1 and 3 to 1-833-256-2747

For Patients
Alnylam Assist® Enrollment

Sections 1 and 2 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):			Date of Birth (MM/DD/YYYY):
Lawrence N. Reele			05/14/1956
Email: LNReele@email.com		Language Translation? ☑ Yes, translation needed ☐ No If yes, please indicate language: Portuguese	
Street Address: 1020 Generic Ave.	City: Springfield	State: MA	ZIP Code: 15123
Mobile Phone Number: ☑ Preferred ☐ Okay to leave message (555) 137-1634		Alternative Phone Number (if available): ☐ Preferred ☐ Okay to leave message (555) 136-1522	
Caregiver Name (optional): Diane Reele		Caregiver Relationship to Patient (optional): Wife	
Caregiver Phone Number (optional): ☐ Preferred ☐ Okay to leave message (555) 137-1634		Caregiver Email (optional):	

I have read and agree to the Patient Authorization and Support Program Authorization on page 2

SIGN HERE | 01/01/2024 | LAWRENCE N. REELE

Patient/Legal Representative Signature | **Date (MM/DD/YYYY)** | **Printed Name/Relationship to Patient (if applicable)**

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: 123456789101		Group Number: 12-34567
Policyholder Name (First, MI, Last), if other than the patient:		Policyholder Date of Birth (MM/DD/YYYY):		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 (MM/DD/YYYY):		Insurance Phone Number:
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 (MM/DD/YYYY):		Insurance Phone Number:

Please complete and sign the form, then fax pages 1 and 3 to 1-833-256-2747

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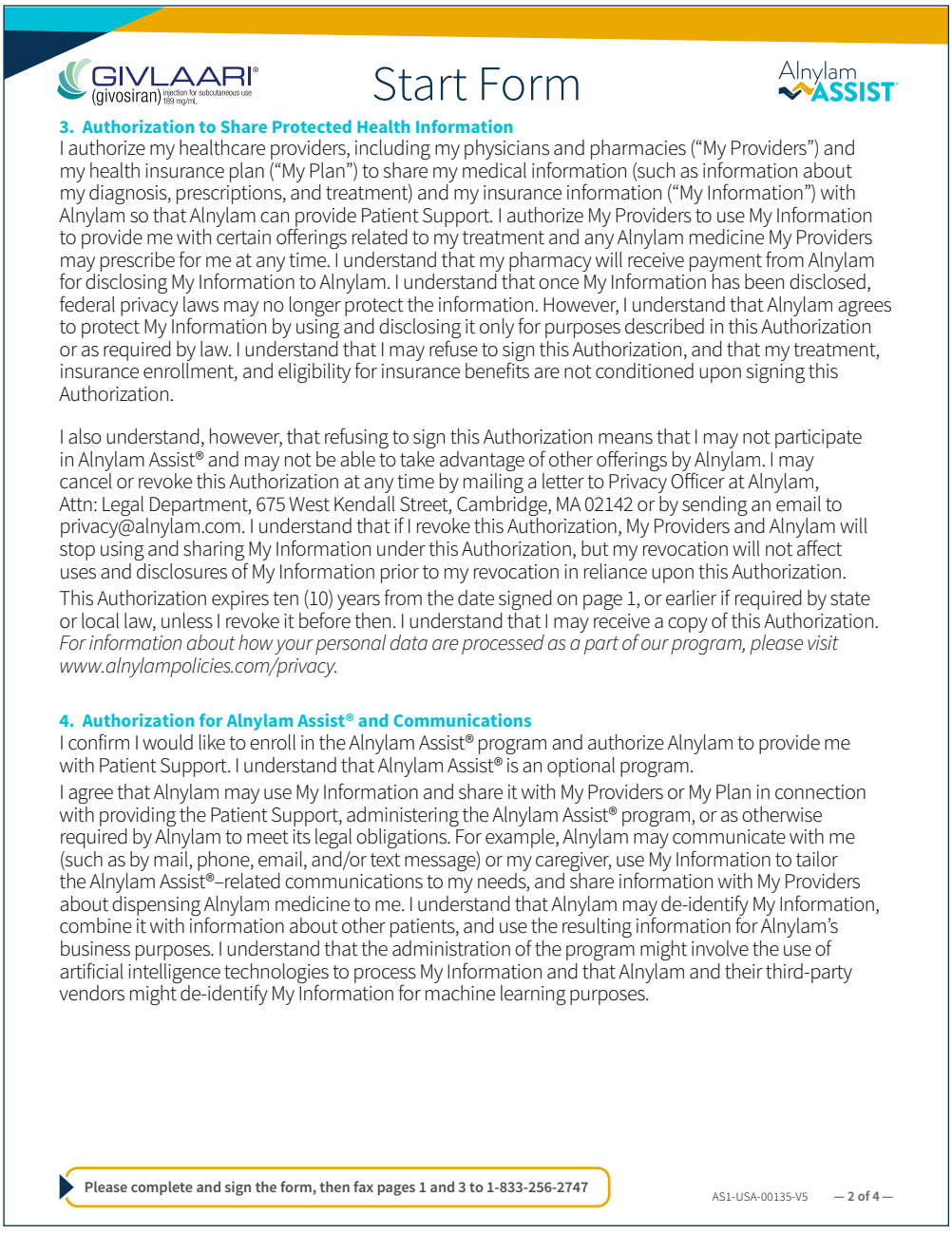
Language Translation
Alnylam Assist® offers translation services for non–English-speaking patients.

Please see Important Safety Information on page 3 and full Prescribing Information.

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

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

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 on page 1, 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 are processed as a part of our program, please visit www.alnylampolicies.com/privacy.*

4. Authorization for Alnylam Assist® and Communications

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, 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. I understand that the administration of the program might involve the use of artificial intelligence technologies to process My Information and that Alnylam and their third-party vendors might de-identify My Information for machine learning purposes.

Please complete and sign the form, then fax pages 1 and 3 to 1-833-256-2747

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Please see Important Safety Information on page 3 and full Prescribing Information.

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

For healthcare providers

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

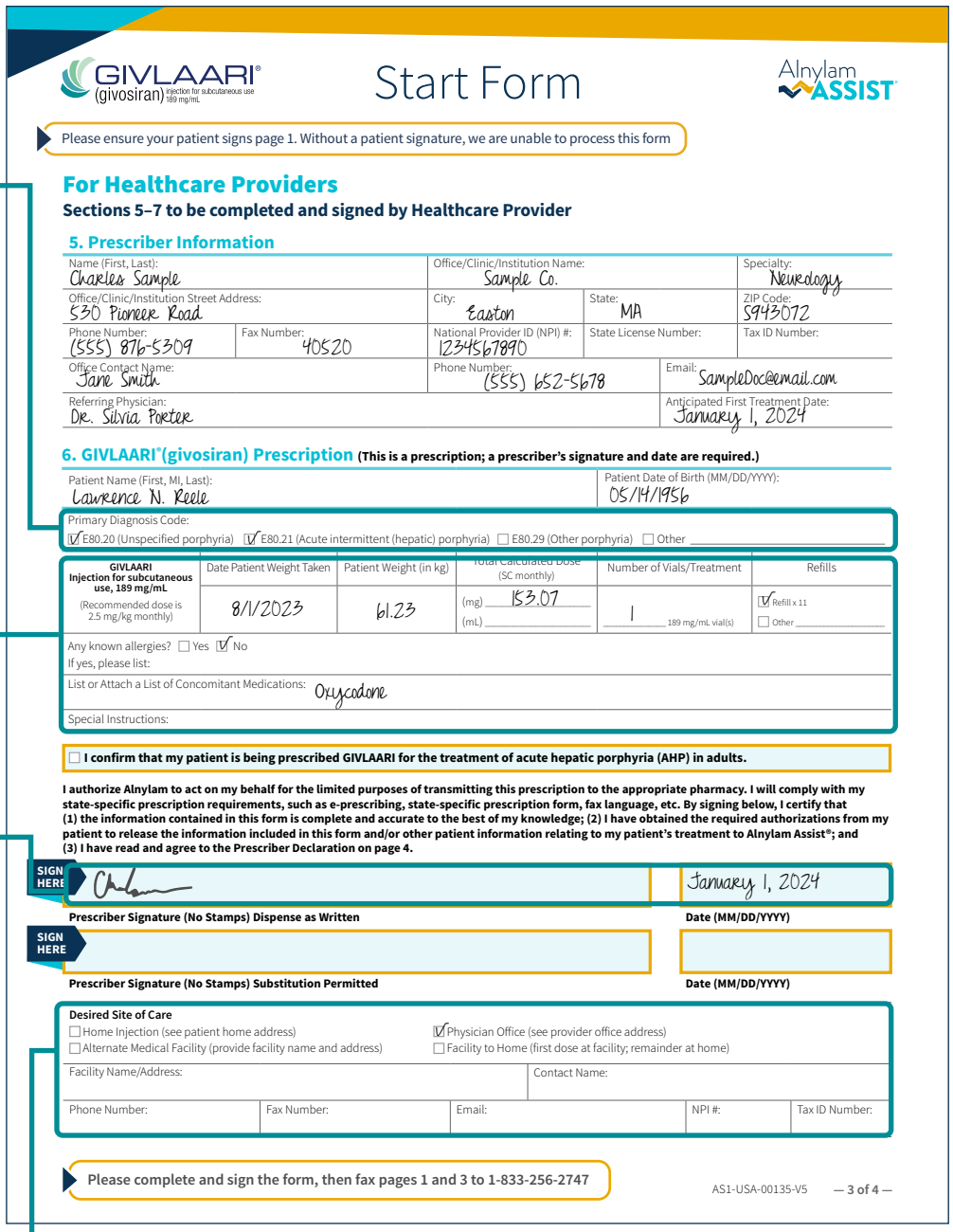
Ensure you fill in this prescription field for your patients.

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

Please ensure your patient signs page 1. Without a patient signature, we are unable to process this form

For Healthcare Providers

Sections 5–7 to be completed and signed by Healthcare Provider

5. Prescriber Information

Name (First, Last): Charles Sample	Office/Clinic/Institution Name: Sample Co.		Specialty: Neurology
Office/Clinic/Institution Street Address: 530 Pioneer Road	City: Easton	State: MA	ZIP Code: 5943072
Phone Number: (555) 876-5309 / Fax Number: 40520	National Provider ID (NPI) #: 1234567890	State License Number:	Tax ID Number:
Office Contact Name: Jane Smith	Phone Number: (555) 652-5678	Email: SampleDoc@email.com	
Referring Physician: Dr. Silvia Porter		Anticipated First Treatment Date: January 1, 2024	

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

Patient Name (First, MI, Last): Lawrence N. Reele

Patient Date of Birth (MM/DD/YYYY): 05/14/1956

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:

☐ **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. By signing below, I certify that (1) the information contained in this form is complete and accurate to the best of my knowledge; (2) I have obtained the required authorizations from my patient to release the information included in this form and/or other patient information relating to my patient's treatment to Alnylam Assist®; and (3) I have read and agree to the Prescriber Declaration on page 4.

SIGN HERE — January 1, 2024

Prescriber Signature (No Stamps) Dispense as Written — **Date (MM/DD/YYYY)**

SIGN HERE

Prescriber Signature (No Stamps) Substitution Permitted — **Date (MM/DD/YYYY)**

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:	Contact Name:			
Phone Number:	Fax Number:	Email:	NPI #:	Tax ID Number:

Please complete and sign the form, then fax pages 1 and 3 to 1-833-256-2747

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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 3 and full Prescribing Information.

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

Prescriber declaration

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

Alnylam ASSIST

7. Prescriber Declaration

By signing on page 3, I certify that: 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 also 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 authorization to allow Alnylam Assist® to contact the patient or caregiver for a signed Patient Authorization, if not already included.

Once you and your patient have completed and signed the form, fax pages 1 and 3 to

1-833-256-2747

Call Alnylam Assist® at 1-833-256-2748
8AM–6PM, Monday–Friday
For more information, visit **www.AlnylamAssist.com/hcp**

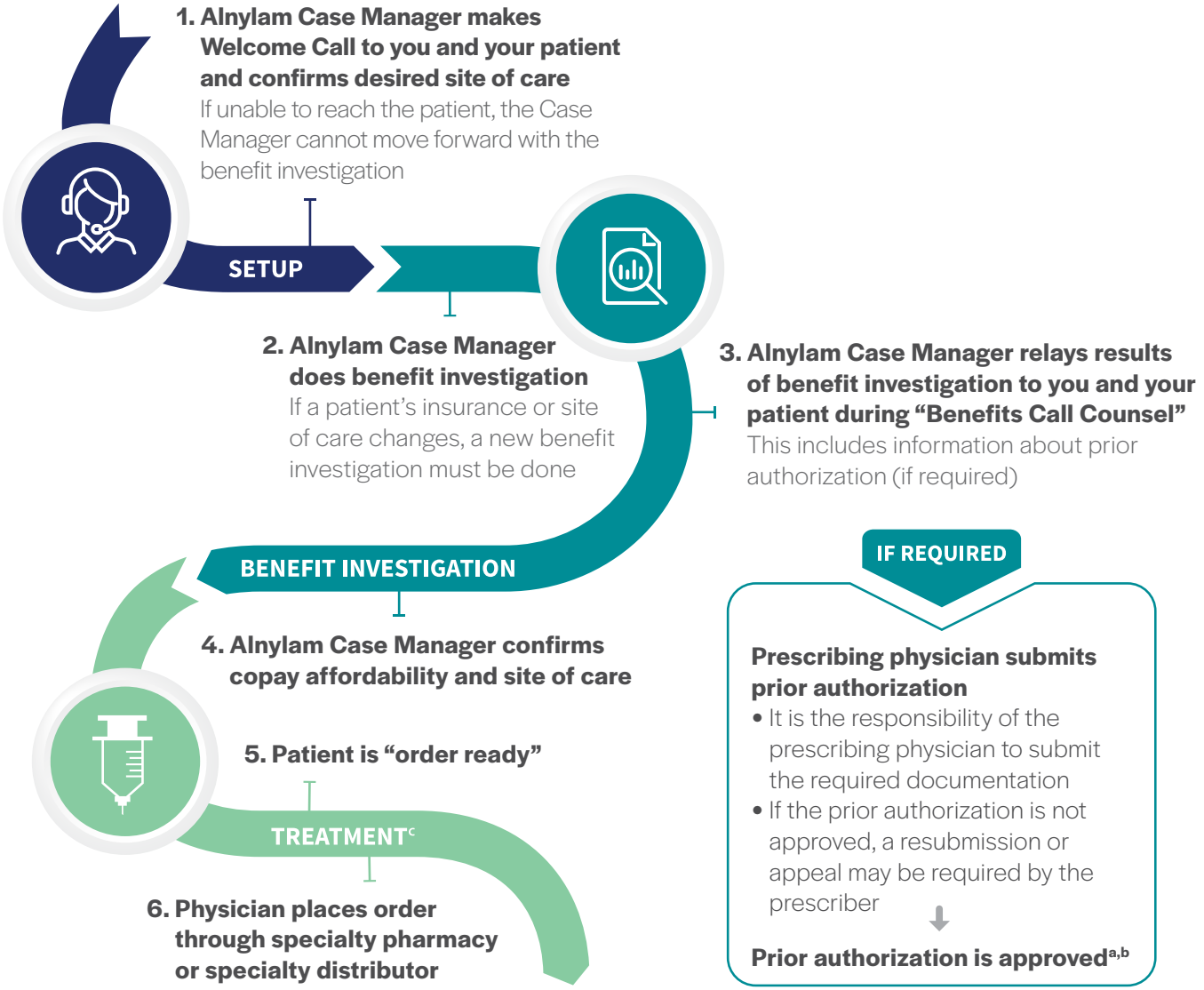
Alnylam PHARMACEUTICALS

— 4 of 4 —

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Once the completed Start Form is received by Alnylam Assist®



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.

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Overview of Acquisition Process for GIVLAARI® (givosiran)

Please see Important Safety Information on page 3 and full Prescribing Information.

Overview of acquisition process

1. Identify a medically appropriate patient for GIVLAARI® (givosiran)

- GIVLAARI is indicated for the treatment of adults with acute hepatic porphyria (AHP)

2. Verify insurance benefits

- Submit Start Form to Alnylam Assist®
- Within 2 business days after Start Form submission, an Alnylam Case Manager will reach out to you and your patient. Following a benefit investigation, you will receive a copy of your patient's Summary of Benefits and Coverage, including prior authorization and payer requirements, as well as financial program information for eligible patients
- Coverage for GIVLAARI will vary by plan and by patient

3. Obtain GIVLAARI

- Specialty Distributor: **McKesson**—healthcare professional can order from McKesson Corporation (specifically, McKesson Specialty Care and McKesson Plasma and Biologics)
- Specialty Pharmacy: either **Accredo** or **PANTHERx** will coordinate drug shipment with healthcare professional

NOTE: GIVLAARI is obtained via a limited network of distributors highlighted above.

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Alnylam ASSIST®

Monday–Friday, 8AM–6PM

: 1-833-256-2748 | : 1-833-256-2747

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

Please see Important Safety Information on page 3 and full Prescribing Information.

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

Alnylam® PHARMACEUTICALS