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

BILLING AND CODING GUIDE

Hospital Outpatient Department

Coverage, coding, and payment in the hospital outpatient department

GIVLAARI® (givosiran) received U.S. Food and Drug Administration (FDA) approval on November 20, 2019, and 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 Medicaid or commercial health plan**, GIVLAARI coverage will vary by payer[a]

Payment

Payer Type	Payment Methodology
Medicare	Average Sales Price (ASP) + 6%[c,d]
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]Medicare payments for GIVLAARI will vary for dates prior to July 1, 2020.
[d]Due to the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the sequestration reduction has been suspended from May 1, 2020 through December 31, 2020.

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

Please see Important Safety Information on page 8 and full Prescribing Information.

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Coding

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®[a]	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
HCPCS[b]	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]CPT © 2018 American Medical Association. All rights reserved.
[b]HCPCS codes for GIVLAARI will vary for dates prior to July 1, 2020.

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
- Some payers may require the use of a JW modifier when billing for the unused portion of the single-dose vial (wastage)—providers should contact payers about specific coding and payment policies
- 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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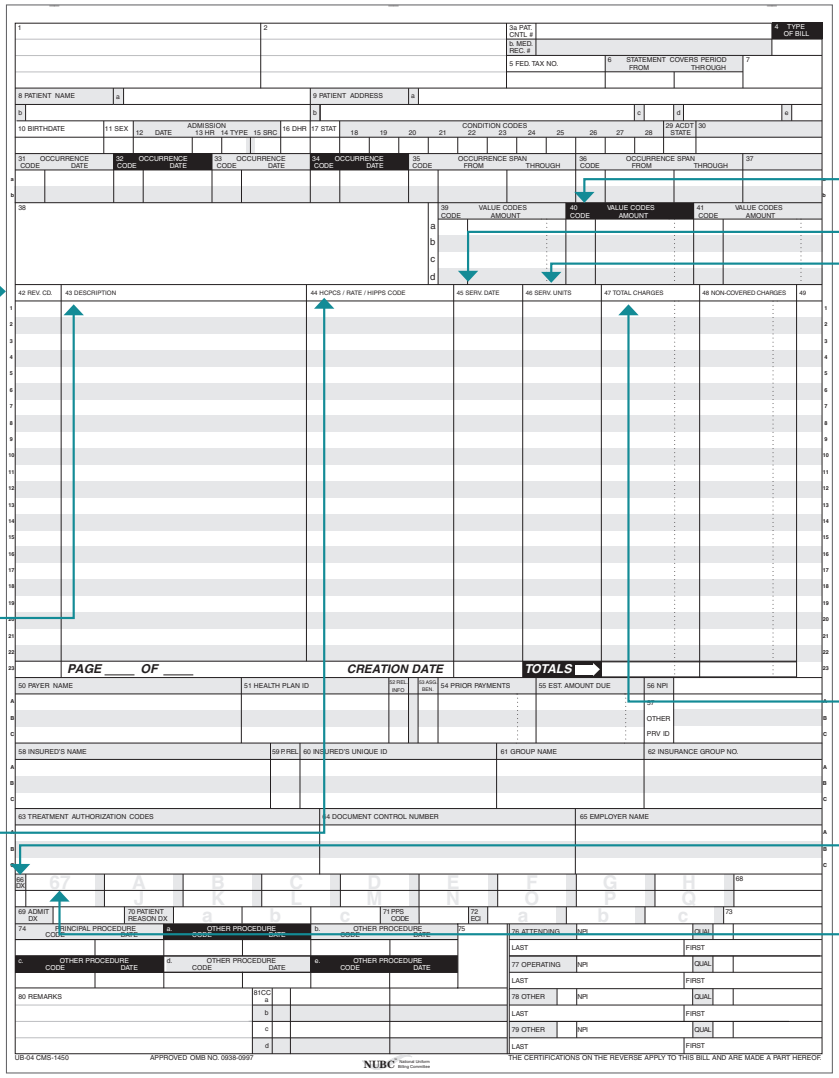
Sample UB-04 Claim Form



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.

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

LOCATOR 40
The first claim line should always be for GIVLAARI® (givosiran) with HCPCS code J0223. The second line should be for the drug administration with CPT code 96372.

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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Loop and segment guide

The table below is a quick loop and segment reference guide for consideration when billing your UB-04 claims electronically. Please be sure to contact your patients' payers to inquire about additional information that may be required.

Information	Code(s) or Additional Information	UB-04 Locator	Electronic Loop	Equivalent Segment
HCPCS	J0223	Locator 44	2400	SV202-2
CPT® Code(s)	96372	Locator 44	2400	SV202-2
HCPCS Level II Code Units	1	Locator 46	2400	SV205
ICD-10-CM Code (primary)	E80.20 E80.21 E80.29	Locator 67	2400	HI01-2
Bill Type Code	Provide specific code	Locator 4	2300	CLM05-1
Revenue Code(s)	0250 0940 0636 Other revenue codes may apply, as appropriate	Locator 42	2400	SV201
NDC Identifier	N4	Locator 43	2410	LIN02
NDC Number	71336-1001-01	Locator 43	2410	LIN03
Quantity/Dosage[a] (Number of NDC units)	Based on patient weight. Refer to GIVLAARI dosing calculation example on page 4	Locator 43	2410	CTP04
Unit of Measure	mL	Locator 43	2410	CTP05-1

[a]The recommended dose of GIVLAARI® (givosiran) is 2.5 mg/kg administered via subcutaneous injection once monthly.

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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[a]**
  - For all claims in the hospital outpatient department setting, use HCPCS code J0223 (Injection, givosiran, 0.5 mg) for dates of service on or after July 1, 2020[b]
    - Remember: Billing Unit = 0.5 mg
  - Remember to use the sample claim form on page 5 as a guide
- **Anticipate requests from payers for additional clinical information prior to claims being processed for payment**

Alnylam **Field Reimbursement Directors** are available to help answer reimbursement-related questions about GIVLAARI® (givosiran). Contact Alnylam Assist® at 1-833-256-2748.

[a]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.
[b]HCPCS codes for GIVLAARI will vary for dates of service prior to July 1, 2020.

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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