

# Billing and Coding Guide

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**Hospital Outpatient Department**



**onpattro**   
(patisiran) lipid complex injection  
10 mg/5 mL

# Coverage, coding, and payment in the hospital outpatient department

ONPATTRO® (patisiran) received US Food and Drug Administration (FDA) approval on 10 Aug 2018, and is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

## Coverage

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

## Payment

Payer Type	Payment Methodology
Medicare	Average Sales Price (ASP) + 6% <sup>c</sup>
Medicaid and Commercial Payers	Payment rates will vary by payer and provider contract

<sup>a</sup>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.

<sup>b</sup>Medicare Advantage plans may require prior authorization for ONPATTRO.

<sup>c</sup>Medicare payment for ONPATTRO will vary for dates of service before April 1, 2019. Does not account for sequestration.

Alylam **Field Reimbursement Directors** are available to meet with you and your staff to answer any reimbursement-related questions about ONPATTRO. Contact Alylam Assist™ at 1-833-256-2748.

Please see Important Safety Information on the last page and full [Prescribing Information](#).

## Coding

Please refer to the table below to support appropriate claims submission for ONPATTRO® (patisiran).

Code Type	Code	Code Description
ICD-10-CM	E85.1	Neuropathic hereditary amyloidosis
CPT <sup>d,e</sup>	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	+96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour
	+96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour
	96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion
	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	+96415	Chemotherapy administration, intravenous infusion technique; each additional hour
	HCPCS <sup>f</sup>	C9399
C9036		ONPATTRO (patisiran) injection for dates of service effective 1/1/19
J3490		Unclassified drugs
J1094		Dexamethasone <sup>g</sup>
J1200		Diphenhydramine <sup>g</sup>
J2780		Ranitidine <sup>g</sup>
Revenue	0250	General pharmacy
	0260	Intravenous therapy
	0636	Drugs requiring detailed coding
NDC <sup>h</sup>	10-digit: 71336-1000-1 11-digit: 71336-1000-01	10 mg/5 mL (2 mg/mL) single-dose vial

<sup>d</sup>CPT © 2014 American Medical Association. All rights reserved.

<sup>e</sup>One-hour code covers up to 90 minutes.

<sup>f</sup>Claims submitted with miscellaneous code C9399 should include product name, route of administration, and dosage in mL and NDC (NDC 71336-1000-01) in Locator 80 on the UB-04 claim form. Providers should contact commercial payers and Medicaid agencies for specific information on reporting drugs using miscellaneous HCPCS codes.

<sup>g</sup>For premedications not available or not tolerated intravenously, equivalents may be administered orally.

<sup>h</sup>Given all the different possible sources for J1094, J1200, and J2780 NDCs as well as different HCPCS codes for premedications, please consult with an Alnylam Field Reimbursement Director or the manufacturers for the applicable NDC and HCPCS codes.

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.

# Hospital outpatient: sample UB-04 claim form

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

- The following UB-04 claim form for ONPATTRO 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

- ONPATTRO is supplied as a 10 mg/5 mL (2 mg/mL) solution in a single-dose vial
- The recommended dose of ONPATTRO is 0.3 mg/kg administered via intravenous (IV) infusion over ~80 minutes once every three weeks
- Dosing is based on actual body weight. For patients weighing  $\geq 100$  kg, the recommended dose is 30 mg

## Calculation

How to calculate mg	How to calculate mL
$(\text{body weight (kg)} \times 0.3 \text{ mg/kg}) = \text{mg}$	$(\text{mg} \times 5 \text{ mL}/10 \text{ mg}) = \text{mL}$

Proper preparation of ONPATTRO requires filtration to remove particulates. An additional vial may be required depending on the type of filter used and the amount of product that remains in the filter (hold-up volume). The calculator found in the ONPATTRO Dosing & Administration Guide assumes that 1 mL of drug product remains in the filter when determining the number of vials needed.

## Example - 68 kg patient

mg	mL
$68 \text{ kg} \times 0.3 \text{ mg/kg} = 20.4 \text{ mg}$	$20.4 \text{ mg} \times 5 \text{ mL}/10 \text{ mg} = 10.2 \text{ mL}$

Please see Important Safety Information on the last page and full [Prescribing Information](#).

## 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 ONPATTRO 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 Medicare:**

C9399—Unclassified drugs and biologics for dates of service between 8/10/18 and 12/31/18.  
C9036—ONPATTRO injection for dates of service between 1/1/19 and 12/31/19.

**For Medicaid and Commercial Payers:**  
J3490—Unclassified drugs.

## Sample UB-04 Claim Form

The image shows a sample UB-04 Claim Form with various sections and callouts. The callouts are as follows:

- LOCATOR 40:** Points to the 41 CODE column in the 38 VALUE CODES AMOUNT section.
- LOCATOR 45:** Points to the 45 SERV DATE column in the 43 DESCRIPTION section.
- LOCATOR 46:** Points to the 46 SERV UNITS column in the 43 DESCRIPTION section.
- LOCATOR 47:** Points to the 47 TOTAL CHARGES column in the 43 DESCRIPTION section.
- LOCATOR 48:** Points to the 48 NON-COVERED CHARGES column in the 43 DESCRIPTION section.
- LOCATOR 49:** Points to the 49 TOTAL CHARGES column in the 43 DESCRIPTION section.
- LOCATOR 50:** Points to the 50 PAYER NAME column in the 50 PAYER NAME section.
- LOCATOR 51:** Points to the 51 HEALTH PLAN ID column in the 50 PAYER NAME section.
- LOCATOR 52:** Points to the 52 CREATION DATE column in the 50 PAYER NAME section.
- LOCATOR 53:** Points to the 53 TOTALS column in the 50 PAYER NAME section.
- LOCATOR 54:** Points to the 54 PRIOR PAYMENTS column in the 50 PAYER NAME section.
- LOCATOR 55:** Points to the 55 EST. AMOUNT DUE column in the 50 PAYER NAME section.
- LOCATOR 56:** Points to the 56 NPI column in the 50 PAYER NAME section.
- LOCATOR 57:** Points to the 57 OTHER column in the 50 PAYER NAME section.
- LOCATOR 58:** Points to the 58 INSURED'S NAME column in the 58 INSURED'S NAME section.
- LOCATOR 59:** Points to the 59 IRL column in the 58 INSURED'S NAME section.
- LOCATOR 60:** Points to the 60 INSURED'S UNIQUE ID column in the 58 INSURED'S NAME section.
- LOCATOR 61:** Points to the 61 GROUP NAME column in the 58 INSURED'S NAME section.
- LOCATOR 62:** Points to the 62 INSURANCE GROUP NO. column in the 58 INSURED'S NAME section.
- LOCATOR 63:** Points to the 63 TREATMENT AUTHORIZATION CODES column in the 63 TREATMENT AUTHORIZATION CODES section.
- LOCATOR 64:** Points to the 64 DOCUMENT CONTROL NUMBER column in the 63 TREATMENT AUTHORIZATION CODES section.
- LOCATOR 65:** Points to the 65 EMPLOYER NAME column in the 63 TREATMENT AUTHORIZATION CODES section.
- LOCATOR 66:** Points to the 66 ICD-10-CM diagnosis coding system column in the 66 ICD-10-CM diagnosis coding system section.
- LOCATOR 67:** Points to the 67 PRIMARY DIAGNOSIS CODE column in the 66 ICD-10-CM diagnosis coding system section.
- LOCATOR 68:** Points to the 68 OTHER PROCEDURE CODE column in the 68 OTHER PROCEDURE CODE section.
- LOCATOR 69:** Points to the 69 OTHER PROCEDURE DATE column in the 68 OTHER PROCEDURE CODE section.
- LOCATOR 70:** Points to the 70 OTHER PROCEDURE CODE column in the 68 OTHER PROCEDURE CODE section.
- LOCATOR 71:** Points to the 71 OTHER PROCEDURE DATE column in the 68 OTHER PROCEDURE CODE section.
- LOCATOR 72:** Points to the 72 OTHER PROCEDURE CODE column in the 68 OTHER PROCEDURE CODE section.
- LOCATOR 73:** Points to the 73 OTHER PROCEDURE DATE column in the 68 OTHER PROCEDURE CODE section.
- LOCATOR 74:** Points to the 74 REMARKS column in the 74 REMARKS section.
- LOCATOR 75:** Points to the 75 ICD-10-CM diagnosis coding system column in the 75 ICD-10-CM diagnosis coding system section.
- LOCATOR 76:** Points to the 76 PRIMARY DIAGNOSIS CODE column in the 75 ICD-10-CM diagnosis coding system section.
- LOCATOR 77:** Points to the 77 OPERATING NPI column in the 77 OPERATING NPI section.
- LOCATOR 78:** Points to the 78 OTHER NPI column in the 78 OTHER NPI section.
- LOCATOR 79:** Points to the 79 OTHER NPI column in the 79 OTHER NPI section.
- LOCATOR 80:** Points to the 80 REMARKS column in the 80 REMARKS section.

## LOCATOR 40

There are 3 different scenarios for CPT® codes (listed below). For each, the first claim line should always be for ONPATTRO® (patisiran) with J3490 followed by the premed HCPCS codes.

- 96365/96366 and 96367 combination
- 96413/96415 and 96367 combination
- 96379 scenario

## 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.

## LOCATOR 80

Until a permanent HCPCS code for ONPATTRO is issued, enter the product name, route of administration, dosage in mL (refer to example on the left to find out how to calculate dosing), and NDC (NDC 71336-1000-01). Confirm with the payer whether additional information is required in this field (e.g., wastage, invoice price, strength in mg/mL).

# Loop and segment guide

## Important considerations when including NDC information along with unlisted codes on your UB-04 claims

Medicare and commercial insurers require that additional information be included on your claims when billing NDCs, especially when the corresponding HCPCS code is a Not Otherwise Classified (NOC) code like C9399 (Medicare) or J3490 (commercial insurers). In addition, some payers may also require that unlisted CPT® code 96379 be used to report an ONPATTRO® (patisiran) infusion.

The table below is a quick loop and segment reference guide 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 or CPT® Code	For Medicare: C9399 or C9036 and/or 96379 <sup>a</sup> For Medicaid and Commercial Payers: J3490 and/or 96379 <sup>a</sup>	Locator 44	2400	SV-202-2
Unlisted CPT® Code Descriptor <sup>b</sup>	ONPATTRO IV, NDC 71336-1000-01, X mL dose, Xmg strength <sup>c</sup>	Locator 44	2400	SV202-7
CPT® Code(s)	96365/96366/96367 96413/96415/96367	Locator 44	2400	SV202-2
HCPCS Level II Code Units	1	Locator 46	2400	SV205
Additional Product Information <sup>b</sup>	ONPATTRO IV, NDC 71336-1000-01, X mL dose, Xmg strength <sup>c</sup>	Locator 80	2300	NTE01 and NTE02
ICD-10-CM Code (primary)	E85.1	Locator 67	2400	HI01-2
Bill Type Code	Provide specific	Locator 4	2300	CLM05-1
Revenue Code(s)	0250 0260 0636 Other revenue codes may apply, as appropriate	Locator 42	2400	SV201
NDC Identifier	N4	Locator 43	2410	LIN02
NDC Number	71336-1000-01	Locator 43	2410	LIN03
Quantity/Dosage <sup>c</sup> (Number of NDC units)	Based on patient weight. Refer to ONPATTRO dosing calculation example on page 4	Locator 43	2410	CTP04
Unit of Measure	mL	Locator 43	2410	CTP05-1

<sup>a</sup>When required.

<sup>b</sup>Payers may prefer that unlisted CPT® Code and NOC descriptors be included in one loop/segment combination over another. Including ONPATTRO IV, NDC 71336-1000-01, X mL dose, Xmg strength in both sections of your electronic claims is acceptable and ensures you are submitting this important information to payers.

<sup>c</sup>The recommended dose of ONPATTRO is 0.3 mg/kg. For patients weighing ≥100 kg, the recommended dose is 30 mg.

Please see Important Safety Information on the last page and full [Prescribing Information](#).

# 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 Medicare claims in the hospital outpatient department (HOPD), use C9399 as the miscellaneous HCPCS code for dates of service between 8/10/18 and 12/31/18
    - Remember: Billing Unit = 1
  - For Medicare claims in the HOPD, use C9036 as the product-specific C-code for ONPATTRO® (patisiran) injection for dates of service effective 1/1/19
    - Remember: Billing Unit = 0.1 mg
  - In general, commercial and Medicaid payers will require the use of J3490 (Unclassified drugs) in the HOPD setting
  - If using a miscellaneous code, make sure Locator 80<sup>d</sup> (UB-04) is unlocked and available for use within the billing software
    - Properly document the 11-digit NDC, product name, route of administration, and dosage in mL (see page 4 for example of dosing calculation)
  - 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

Anylam **Field Reimbursement Directors** are available to help answer any reimbursement-related questions you may have about ONPATTRO. Contact Anylam Assist™ at 1-833-256-2748.

<sup>d</sup>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.



8AM–7PM ET, Monday–Friday  
☎: 1-833-256-2748 | 📠: 1-833-256-2747

To learn more about ONPATTRO® (patisiran),  
visit [www.onpattro.com](http://www.onpattro.com).

## Indication

ONPATTRO® (patisiran) is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

## Important Safety Information

### Infusion-Related Reactions

Infusion-related reactions (IRRs) have been observed in patients treated with ONPATTRO. In a controlled clinical study, 19% of ONPATTRO-treated patients experienced IRRs, compared to 9% of placebo-treated patients. The most common symptoms of IRRs with ONPATTRO were flushing, back pain, nausea, abdominal pain, dyspnea, and headache.

To reduce the risk of IRRs, patients should receive premedication with a corticosteroid, acetaminophen, and antihistamines (H1 and H2 blockers) at least 60 minutes prior to ONPATTRO infusion. Monitor patients during the infusion for signs and symptoms of IRRs. If an IRR occurs, consider slowing or interrupting the infusion and instituting medical management as clinically indicated. If the infusion is interrupted, consider resuming at a slower infusion rate only if symptoms have resolved. In the case of a serious or life-threatening IRR, the infusion should be discontinued and not resumed.

### Reduced Serum Vitamin A Levels and Recommended Supplementation

ONPATTRO treatment leads to a decrease in serum vitamin A levels. Supplementation at the recommended daily allowance (RDA) of vitamin A is advised for patients taking ONPATTRO. Higher doses than the RDA should not be given to try to achieve normal serum vitamin A levels during treatment with ONPATTRO, as serum levels do not reflect the total vitamin A in the body.

Patients should be referred to an ophthalmologist if they develop ocular symptoms suggestive of vitamin A deficiency (e.g. night blindness).

### Adverse Reactions

The most common adverse reactions that occurred in patients treated with ONPATTRO were upper respiratory tract infections (29%) and infusion-related reactions (19%).

Please see full [Prescribing Information](#) for additional information.