

Billing and Coding Guide

Physician Office



onpattro[®]
(patisiran) lipid complex injection
10 mg/5 mL

Coverage, coding, and payment in the physician office

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^{a,b}
- **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% ^c
Medicaid and Commercial Payers	Payment rates will vary by payer and provider contract

^aIt 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.

^bMedicare Advantage plans may require prior authorization for ONPATTRO.

^cMedicare payment for ONPATTRO will vary for dates of service before April 1, 2019. Does not account for sequestration.

Amylam **Field Reimbursement Directors** are available to meet with you and your staff to answer any reimbursement-related questions about ONPATTRO. Contact Amylam 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 ^{d,e}	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 ^f	J3490
J1094		Dexamethasone ^g
J1200		Diphenhydramine ^g
J2780		Ranitidine ^g
NDC ^h	10-digit: 71336-1000-1 11-digit: 71336-1000-01	10 mg/5 mL (2 mg/mL) single-dose vial

^dCPT © 2014 American Medical Association. All rights reserved.

^eOne-hour code covers up to 90 minutes.

^fClaims submitted with miscellaneous codes, including J3490, should include the product name, route of administration, dosage in mL, and NDC (NDC 71336-1000-01) in Locator 19 on the CMS-1500 claim form. Providers should contact commercial payers and Medicaid agencies for specific information on reporting drugs using miscellaneous HCPCS codes.

^gFor premedications not available or not tolerated intravenously, equivalents may be administered orally.

^hGiven all the different possible sources for J1094, J1200, and J2780 NDCs as well as different HCPCS codes for premedications, please consult with an Anylam 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.

Physician office: sample CMS-1500 claim form

ONPATTRO® (patisiran) 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 ONPATTRO is provided on the next page.

- The following CMS-1500 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 that 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 ≥ 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](#).

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 24_{A-B}

Enter the date of service and the appropriate place of service code.

LOCATOR 24_E

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

LOCATOR 24_G

Enter the number of service units for each line item.

When billing a miscellaneous HCPCS code, report a unit of 1.

When billing J1094, report 10 days/units.

When billing J1200, report 1 day/unit.

When billing J7280, report 2 days/units.

The image shows a sample CMS-1500 Health Insurance Claim Form. Green callout boxes point to specific fields:

- Locator 21: Points to the ICD-10-CM code field (21A) and the ICD-IND field (21B).
- Locator 24_{A-B}: Points to the date of service (24A) and the place of service code (24B).
- Locator 24_E: Points to the diagnosis field (24E).
- Locator 24_G: Points to the units field (24G).

LOCATOR 24_D

Enter the appropriate HCPCS code for ONPATTRO.

For Medicare, Medicaid, and Commercial Payers:
 J3490—Unclassified drugs
 S HCPCS—If developed (Commercial and Medicaid plans only)

Enter the appropriate HCPCS for premeds:

J1094—Dexamethasone/Decadron
 J1200—Diphenhydramine/Benadryl
 J7280—Ranitidine/Zantac

Shaded area of Locator 24D: N471336100001 X mL

LOCATOR 19

Until a permanent HCPCS code for ONPATTRO® (patisiran) is issued, enter the product name, dosage in mL (refer to example in lower left to calculate dosing), route of administration, 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).

Example information

IV administration ONPATTRO, NDC 71336-1000-01, X mL dose, strength X mg/mL

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

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

Tips for Locator 19

- Most payers require that the Locator 19 information be submitted using Loop 2400/Segment SV101-7. Some payers require that you utilize Loop 2400/Segment NTE02
- Please be sure to contact your billing software vendor to ensure this field is populated correctly by utilizing the recommended loops and segments
- Locator 19 can only hold up to 80 characters (including spaces). The sample Locator 19 information provided equals 71 characters. Be sure to check with your billing software vendor to ensure that your system currently enables you to enter this many characters, as some programs may require an upgrade

Loop and segment guide

Important considerations when including NDC information along with unlisted codes on your CMS-1500 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 J3490. 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 for use when billing your CMS-1500 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	CMS-1500 Locator	Electronic Loop	Equivalent Segment
HCPCS or CPT® Code	J3490 and/or 96379 ^a	Locator 24 D	2400	SV101-2
Unlisted CPT® Code Descriptor ^b	ONPATTRO IV, NDC 71336-1000-01, XmL dose, Xmg strength ^b	Locator 19	2400	SV101-7 or NTE02 ^b
CPT® Code(s)	96365/96366/96367 96413/96415/96367	Locator 24 D	2400	SV101-2
HCPCS Level II Code Units	1	Locator 24 G	2400	SV104
ICD-10-CM Code (primary)	E85.1	Locator 21	2400	HI01-2
NDC Identifier	N4	Shaded area above claim line for J3490 in Locator 24 A	2410	LIN02
NDC Number	71336-1000-01	Shaded area above claim line for J3490 in Locator 24 A	2410	LIN03
Quantity/Dosage ^b (Number of NDC units)	Based on patient weight. Refer to ONPATTRO dosing calculation example on page 4	Shaded area above claim line for J3490 in Locator 24 A	2410	CTP04
Unit of Measure	mL	Shaded area above claim line for J3490 in Locator 24 A	2410	CTP05-1

^aWhen required.

^bThe majority of payers require that the Locator 19 information above be submitted to them by using **Loop 2400**/Segment SV101-7. However, there may be other payers that require you to use **Loop 2400**/Segment NTE02.

- **Best practice tip:** For more details on the correct loop and segment to use, be sure to review your patients' payer provider manuals, specifically regarding clean claim submission requirements
- **Best practice tip:** Remember to contact your billing software vendor and relay the loop/segment information provided. They can provide useful information on how to enter this information correctly

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®, and HCPCS codes
 - In general, most payers will require the use of J3490 (Unclassified drugs) in the physician office setting^c
 - Remember: Billing unit = 1
 - If using a miscellaneous code, make sure Locator 19^c (CMS-1500) 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

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

^cIt 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.

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