Patisiran (Onpattro®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Hospital Outpatient Facility Administration HCPCS: J0222 per 0.1 mg

Condition listed in policy (*see criteria for details*)

- Hereditary transthyretin amyloidosis (hATTR) with polyneuropathy

AHFS therapeutic class: Amyloidosis agent, transthyretin (TTR) suppression

Mechanism of action: Transthyretin-directed small interfering RNA

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for patisiran (Onpattro®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Hereditary transthyretin amyloidosis (hATTR) with polyneuropathy

1. Age 18 years or older, **AND**
2. Prescribed by or in consultation with a neurologist, **AND**
3. Documented diagnosis of hATTR with polyneuropathy confirmed by documentation of a pathogenic TTR mutation, **AND**
4. Not being used in combination with Tegsedi or tafamidis

Covered Doses

- <100 kg: up to 0.3 mg/kg IV every 3 weeks
- ≥100 kg: up to 30 mg IV every 3 weeks

Coverage Period
Indefinite

ICD-10:
E85.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for patisiran (Onpattro®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 10 mg/5 mL (2 mg/mL) solution in a single-dose glass vial.

(6) References

- Adams D, Suhr OB, Hund E, et al. First European consensus for diagnosis, management, and treatment of transthyretin familial amyloid polyneuropathy. Curr Opin Neurol. 2016;29(Suppl 1):S14-26.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Onpattro®. [Prescribing information]. Alnylam Pharmaceuticals, Inc.: Cambridge, MA. 5/2021.

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee