blue california
Promise Health Plan

## patisiran (Onpattro)

## Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Hospital Outpatient Facility Administration
Infusion Center Administration
Office Administration

## Drug Details

**USP Category:** CENTRAL NERVOUS SYSTEM AGENTS
**Mechanism of Action:** Transthyretin-directed small interfering RNA
**HCPCS:**
J0222:Injection, patisiran, 0.1 mg
**How Supplied:**
10 mg/5 mL (single-dose)

## Condition(s) listed in policy *(see coverage criteria for details)*

- Hereditary Transthyretin Amyloidosis (hATTR) with Polyneuropathy

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

## Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

## Coverage Criteria
**The following condition(s) require Prior Authorization/Preservice.**

**Hereditary Transthyretin Amyloidosis (hATTR) with Polyneuropathy**
**Meets medical necessity if all the following are met:**
1. Age is consistent with the FDA-approved indication
2. Prescribed by or in consultation with a neurologist
3. Diagnosis of hATTR with polyneuropathy confirmed by a pathogenic TTR mutation
4. Not being used in combination with another TTR silencer or TTR stabilizer [tafamidis (Vyndaqel, Vyndamax)

**Covered Doses:**

- Less than 100 kg: up to 0.3 mg/kg given intravenously every 3 weeks
- 100 kg or greater: up to 30 mg given intravenously every 3 weeks

**Coverage Period:**
Yearly, based on continued response to therapy

**ICD-10:**
E85.1

## References


1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Onpattro (patisiran) Prescribing Information. Alnylam Pharmaceuticals, Inc., Cambridge, MA: 1/2023.


## Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity*
*Reviewed by P&T Committee*