SmartHealth Ascension

Patisiran

(Onpattro®) J0222 (0.1mg)

Covered with prior authorization

Patisiran (Onpattro®) may be authorized when the following criteria are met:

Initial Requests:

Individual has a diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP); AND

- Documentation is provided that individual has a TTR mutation confirmed by genotyping (e.g., V30M, A97S, T60A, E89Q, S50R); **AND**
- Documentation is provide that individual has associated mild to moderate polyneuropathy; **AND**
- Member must be 18 years of age and older; **AND**
- Prescribed by or in consultation with a neurologist or a specialist in the treatment of amyloidosis.

Continuation of therapy requests:

- Documentation is provided to show clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improved ambulation, improvement in neurologic symptom burden, improvement in activities of daily living).

Exclusion criteria:

Requests for Patisiran (Onpattro®) may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use
- Individual has a history of liver transplantation
- Individual has severe renal impairment or end-stage renal disease
- Individual has moderate or severe hepatic impairment
- Individual has New York Heart Association (NYHA) class III or IV heart failure
- Individual has sensorimotor or autonomic neuropathy not related to hATTR amyloidosis (monoclonal gammopathy, autoimmune disease, etc.)
- Individual is using in combination with Amvuttra, Tegsedi, Vyndaqel or Vyndamax

Initial authorization is up to 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Onpattro® contains a transthyretin-directed small interfering RNA and is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Dosing:

- **For patients weighing < 100 kg: the recommended dosage is 0.3 mg/kg intravenously (IV) once every 3 weeks**
- **For patients weighing ≥ 100 kg: the recommended dosage is 30 mg IV once every 3 weeks**

References:

1. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):11-21.
2. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a Phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017;17(1):181.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Onpattro® [Prescribing Information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc. 2023.

Date	Summary of Changes
January 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
January 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.