Onpattro (patisiran lipid complex)  
(Intravenous)

Document Number: IC-0379

Last Review Date: 10/01/2019  
Date of Origin: 09/05/2018  
Dates Reviewed: 09/2018, 10/2019

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Onpattro 10 mg injection: 3 vials every 3 weeks

B. Max Units (per dose and over time) [Medical Benefit]:
   - 300 billable units every 3 weeks

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Must not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen, tafamidis, etc.); AND

Polyneuropathy due to Hereditary Transthyretin-Mediated (hATTR) Amyloidosis / Familial Amyloidotic Polyneuropathy (FAP) †

- Patient must be at least 18 years old; AND

- Patient has a definitive diagnosis of hATTR amyloidosis/FAP as documented by amyloid deposition on tissue biopsy and identification of a pathogenic TTR variant using molecular genetic testing; AND

- Used for the treatment of polyneuropathy as demonstrated by at least TWO of the following criteria:
  - Subjective patient symptoms are suggestive of neuropathy
  - Abnormal nerve conduction studies are consistent with polyneuropathy
  - Abnormal neurological examination is suggestive of neuropathy; AND
- Patient’s peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded: **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council (MRC) muscle strength, etc.): **AND**
- Patient has not been the recipient of an orthotopic liver transplant (OLT): **AND**
- Patient is receiving supplementation with vitamin A at the recommended daily allowance

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s)

### IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III: **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion-related reactions, ocular symptoms related to hypovitaminosis A, etc.: **AND**
- Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
  - Signs and symptoms of neuropathy
  - MRC muscle strength

### V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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| hATTR/FAP  | **Recommended dosage:**  
  - Weight < 100 kg  
    - 0.3 mg/kg intravenously every 3 weeks  
  - Weight ≥ 100 kg  
    - 30 mg intravenously every 3 weeks  
|             | **Preparing for Therapy:**  
  - Dosing is based on actual body weight  
  - Patients should be premedicated with a corticosteroid, acetaminophen and antihistamines.  
  - Infusion should be filtered and diluted and infused, via a pump, over at least 80 minutes.  
  - Patients should receive vitamin A supplementation. |

### VI. Billing Code/Availability Information

**HCPCS code:**

- J0222 – Injection, patisiran, 0.1 mg; 1 billable unit = 0.1 mg

**NDC:**

- Onpattro 10 mg/5 mL single-dose vial: 71336-1000-xx
VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>E85.1</td>
<td>Neuropathic heredofamilial amyloidosis</td>
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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

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