I. Medication Description

Onpattro (patisiran) is a double-stranded siRNA that causes degradation of mutant and wild-type TTR mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. It is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

II. Policy

Coverage of Onpattro is provided in accordance with the following criteria:

- Member is 18 years of age or older AND
- Medication is prescribed by or in consultation with a pertinent specialist (e.g. neurologist) treating hATTR AND
- Medication is prescribed for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis AND
- hATTR diagnosis has been confirmed by detection of a mutation of the TTR gene AND
- Amyloid deposition has been confirmed in biopsy specimen(s) AND
- Baseline Neuropathy Impairment Score is between 5-130 AND
- Member has a baseline polyneuropathy disability (PND) score ≤ IIIb AND
- Member exhibits clinical manifestations of of the disease (e.g., sensory and motor peripheral neuropathy and/or autonomic neuropathy, motor disability, etc) and other causes of neuropathy have been excluded AND
- Member is not currently taking diflunisal, tafamidis, doxycycline, or tauroursodeoxycholic acid.

IV. Quantity Limitations

Coverage is available for a quantity sufficient to allow for FDA-approved dosing:

- For members weighing less than 100 kg, the recommended dosage is 0.3 mg/kg once every 3 weeks.
- For members weighing 100 kg or more, the recommended dosage is 30 mg once every 3 weeks.
V. Coverage Duration

Initial coverage is available for 9 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed when the following criteria are met:

• First renewal (up to 9 months):
  o Stabilization of disease or absence of disease progression OR
  o Documented Neuropathy Impairment Score improvement AND
  o Absence of unacceptable toxicity from the drug.

• Second and subsequent renewals (up to 12 months):
  o Documented Neuropathy Impairment Score improvement AND
  o Documented positive clinical response (e.g., improved neurologic impairment, motor function, quality of life assessment, serum TTR levels, etc.) AND
  o Absence of unacceptable toxicity from the drug.

VII. Billing/Coding Information

• C9036: 1 billable unit = 0.1mg
• J3490: 1 billable unit = 1 vial
• Pertinent indication:
  o Neuropathic heredofamilial amyloidosis: E85.1
• Available as lipid complex injection: 10 mg/5 mL (2 mg/mL) solution in a single-dose vial.

VIII. Summary of Policy Changes

12/1/2018: new policy
1/3/19: updated billing/coding information
11/15/19: no policy changes

IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.