Onpattro® (patisiran) (Intravenous)

Last Review Date: January 1, 2019  Number: MG.MM.PH.119

Medical Guideline Disclaimer

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Definition

Patisiran was FDA approved for the treatment of the polyneuropathy of hATTR amyloidosis in adults. hATTR amyloidosis is a rapidly progressive, life-threatening disease caused by mutant and wild-type transthyretin (TTR) proteins forming amyloid deposits in tissues throughout the body. More than 95% of TTR circulating in the body is produced by the liver. This amyloid accumulation leads to progressive multisystem dysfunction, including polyneuropathy (e.g., sensorimotor and autonomic neuropathy) and cardiomyopathy. Patisiran is a double-stranded small interfering ribonucleic acid (siRNA) formulated as a lipid nanoparticle complex for delivery to hepatocytes. Patisiran causes the 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.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 30 mg every 3 weeks

Guideline

I. INITIAL APPROVAL CRITERIA

Patisiran may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:

Polyneuropathy of hATTR amyloidosis†

- 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-labeled indication(s);

Limitations/Exclusions
Onpatrro is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

II. RENEWAL CRITERIA

- Patient continues to meet Initial approval criteria.
- Disease response compared to baseline prior to treatment shows improvement or stabilization in one or both of the following:
  - Neuropathy signs and symptoms
  - MRC muscle strength

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>hATTR Amyloidosis</td>
<td><strong>Recommended dosage:</strong></td>
</tr>
<tr>
<td></td>
<td>- Weight &lt; 100 kg</td>
</tr>
<tr>
<td></td>
<td>o 0.3 mg/kg intravenously every 3 weeks</td>
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<tr>
<td></td>
<td>- Weight ≥ 100 kg</td>
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<tr>
<td></td>
<td>o 30 mg intravenously every 3 weeks</td>
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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.

Applicable Procedure Codes

| C9036 | Injection, patisiran, 0.1mg |

Applicable NDCs
Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>E85.1</td>
<td>Neuropathic heredofamilial amyloidosis</td>
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References