Onpattro

Description

Onpattro (patisiran)

Background

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. Onpattro is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults (1).

Regulatory Status

FDA-approved indication: Onpattro contains a transthyretin-directed small interfering RNA and is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults (1).

Infusion-related reactions may occur with Onpattro. Patients should premedicate with a corticosteroid, acetaminophen and antihistamines on the day of Onpattro infusion, at least 60 minutes prior to the start of infusion. Monitor patients during the infusion for signs and symptoms of infusion-related reactions. If one occurs, consider slowing or interrupting the Onpattro infusion and instituting medical management, as clinically indicated. Some patients who experience these reactions may benefit from a slower infusion rate or additional or higher doses of one or more of the premedications with subsequent infusions to reduce the risk of reactions (1).

The safety and effectiveness of Onpattro in pediatric patients have not been established (1).
Onpatro may be considered medically necessary in patients 18 years of age and older with polyneuropathy of hereditary transthyretin-mediated amyloidosis and if the conditions indicated below are met.

Onpatro is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis
The patient must have the following:

Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis

AND ALL of the following:
1. Will be administered by a healthcare professional
2. Patient will receive premedication to reduce the risk of infusion-related reactions
3. Prescriber agrees to supplement the patient with the recommended daily allowance of Vitamin A if indicated
4. NO dual therapy with Tegsedi (inotersen)

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnosis
The patient must have the following:

Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis
AND ALL of the following:
1. Patient has been assessed for improvement and has experienced a clinical benefit from therapy
2. Will be administered by a healthcare professional
3. Patient will receive premedication to reduce the risk of infusion-related reactions
4. Prescriber agrees to supplement the patient with the recommended daily allowance of Vitamin A if indicated
5. NO dual therapy with Tegsedi (inotersen)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 12 vials per 84 days

Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
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. Onpattro is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. The safety and effectiveness of Onpattro in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Onpattro while maintaining optimal therapeutic outcomes.

References
Section: Prescription Drugs  Effective Date: October 1, 2019
Subsection: Neuromuscular Drugs  Original Policy Date: August 24, 2018
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Policy History

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.