Onpattro™ (patisiran)

When requesting Onpattro™ (patisiran), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

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

Approved Off-label Compendial use(s)

None

Coverage Guidelines

The individual must meet **ALL** of the following criteria for approval:

- Diagnosis of hereditary transthyretin-mediated amyloidosis is confirmed by genetic testing; AND
- Has symptomatic peripheral neuropathy (e.g., reduced motor strength/ coordination, impaired sensation [e.g., pain, temperature, vibration, touch]); AND
- Is at least 18 years of age; AND
- Has tried or is currently receiving at least one systemic agent for symptoms of polyneuropathy from one of the following pharmacological classes: a gabapentin-type product (e.g., gabapentin [Neurontin], Lyrica [pregabalin capsules]) or a tricyclic antidepressant (e.g., amitriptyline, nortriptyline); AND
- Onpattro is prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

Approval duration: 12 months

Dosing Recommendations

- 0.3mg/kg IV is administered as an IV infusion once every 3 weeks (maximum dose 30mg)

References

1. Onpattro lipid complex injection, for intravenous use [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; August 2018.
2. Rizk M, Tüzmen Ş. Update on the clinical utility of an RNA interference-based treatment: focus on patisiran. *Pharmgenomics Pers Med*. 2017; 10:267-278.
3. Adams D, Suhr OB, Hund E, et al. First European consensus for diagnosis, management, and treatment of transthyretin familial amyloid polyneuropathy. *Curr Opin Neurol*. 2016; 29 Suppl 1:S14-26.
4. Gertz MA, Benson MD, Dyck PJ, et al. Diagnosis, prognosis, and therapy of transthyretin amyloidosis. *J Am Coll Cardiol*. 2015; 66(21):2451-2466.

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