

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 showing a mutation in the transthyretin (TTR) gene
- Onpattro is being requested for the treatment of polyneuropathy associated with hereditary transthyretin-mediated amyloidosis
- Is at least 18 years of age
- For a re-authorization request, an individual is benefiting from Onpattro treatment (e.g., shown improved measures of polyneuropathy [muscle strength, sensation, reflexes], autonomic function, quality of life, activities of daily living, ambulation, nutritional status)

Approval duration (initial and renewal): 12 months

Dosing Recommendations

Onpattro is administered via intravenous (IV) infusion. Dosing is based on actual body weight.

For patients weighing less than 100 kg, the recommended dosage is 0.3 mg/kg once every 3 weeks.

For patients weighing 100 kg or more, the recommended dosage is 30 mg once every 3 weeks.

[Premedicate with a corticosteroid, acetaminophen, and antihistamines \(both H1 and H2 blockers\).](#)

[Supplement with the recommended daily amount of Vitamin A.](#)

References

1. Onpattro prescribing information. Cambridge, MA: Alnylam Pharmaceutical Inc. August 2018.
2. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a Phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. *BMC Neurology* (2017)17:181 DOI 10.1186/s12883-017-0948-5
3. Butler JS, Chan A, Costelha S, et al. Preclinical evaluation of RNAi as a treatment for transthyretin mediated amyloidosis. *Amyloid*.2016;23(2):109-118.