

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 polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

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 polyneuropathy (e.g., reduced motor strength/ coordination, impaired sensation [e.g., pain, temperature, vibration, touch]). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing; AND
- Is at least 18 years of age; AND
- Onpattro is prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis; AND
- There is no history of liver transplantation.

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® [prescribing information]. Cambridge, MA: Alnylam; May 2021.
2. Alcantara M, Mezi MM, Baker SK, et al. Canadian guidelines for hereditary transthyretin amyloidosis polyneuropathy management. *Can J Neuro Sci.* 2022;49:7-18.
3. Kittleson MM, Maurer MS, Ambardekar AV, et al; on behalf of the American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology. AHA scientific statement: cardiac amyloidosis: evolving diagnosis and management. *Circulation.* 2020;142:e7-e22.
4. McDonagh TA, Metra M, Adamo M, et al. 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J.* 2021;42:3599-3726.
5. Lin H, Merkel M, Hale C, Marantz JL. Experience of patisiran with transthyretin stabilizers in patients with hereditary transthyretin-mediated amyloidosis. *Neurodegener Dis Manag.* 2020;10(5):289-300.