

Amvuttra™ (vutrisiran)

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

FDA-Approved Indication

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

Coverage Guidelines

Hereditary Transthyretin-Mediated Amyloidosis

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

- Diagnosis has been confirmed by genetic testing showing a mutation in the transthyretin gene;
- Has symptomatic polyneuropathy (e.g., reduced motor strength/ coordination, impaired sensation [e.g., pain, temperature, vibration, touch]);
- Is 18 years of age or older;
- Does not have a history of liver transplantation;
- Amvuttra 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 Recommendation

The recommended dose is 25 mg administered by subcutaneous injection once every 3 months.

References

1. Amvuttra™ subcutaneous injection [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals; February 2023.
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.
6. Adams D, Tournev IL, Talor MS, et al. Efficacy and safety of vutrisitan for patients with hereditary transthyretin-mediated amyloidosis with polyneuropathy: a randomized clinical trial. *Amyloid.* 2023; 30(1):1-9.