

Amvuttra® (vutrisiran)

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

FDA-Approved Indications

Amvuttra is indicated for the treatment of:

- the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults;
- the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits.

Coverage Guidelines

Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis

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

- Is 18 years of age or older;
- Has a transthyretin pathogenic variant as confirmed by genetic testing;
- Has symptomatic polyneuropathy (e.g., reduced motor strength/ coordination, impaired sensation [e.g., pain, temperature, vibration, touch]);
- 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.

Cardiomyopathy of Wild-Type or Hereditary Transthyretin-Mediated Amyloidosis

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

- Is 18 years of age or older;
- Diagnosis was confirmed by one of the following:
 - o A technetium pyrophosphate scan (i.e., nuclear scintigraphy); OR
 - o A tissue biopsy with confirmatory transthyretin (TTR) amyloid typing by mass spectrometry, immunoelectron microscopy, or immunohistochemistry; OR
 - o A transthyretin (TTR) pathogenic variant was identified via genetic testing;
- Diagnostic cardiac imaging has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum);
- Has heart failure but does not have New York Heart Association class IV disease;
- Amvuttra is prescribed by or in consultation with a cardiologist 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; March 2025.
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. Adams D, Tournev IL, Talor MS, et al. Efficacy and safety of vutrisiran for patients with hereditary transthyretin-mediated amyloidosis with polyneuropathy: a randomized clinical trial. *Amyloid.* 2023; 30(1):1-9.
5. US Department of Health and Human Services, National Institutes of Health. Transthyretin amyloidosis. Available at: <https://ghr.nlm.nih.gov/condition/transthyretin-amyloidosis#diagnosis>. Accessed on March 21, 2025.
6. Kittleson M, Ruberg FL, Ambardekar AV, et al. A report of the American College of Cardiology Solution Set Oversight Committee. 2023 ACC expert consensus decision pathway on comprehensive multidisciplinary care for the patient with cardiac amyloidosis. *J Am Coll Cardiol.* 2023;81(11):1076-1126.

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