Amvuttra® (vutrisiran)
(Subcutaneous)

Document Number: IC-0670

Last Review Date: 08/04/2026
Date of Origin: 07/05/2022
Dates Reviewed: 07/2022, 10/2023, 07/2024, 05/2025, 07/2026, 08/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 25 billable units (25 mg) every 3 months

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria [1]

- Member is receiving supplementation with vitamin A at the recommended daily allowance; **AND**
- Must not be used in combination with other transthyretin (TTR) reducing or stabilizing agents (e.g., tafamidis, patisiran, acoramidis, inotersen, eplontersen, etc.); **AND**

Polyneuropathy due to Hereditary Transthyretin-Mediated (hATTR) Amyloidosis † Φ [1,5-8]

- Member has a definitive diagnosis of hATTR amyloidosis as documented in a proband with suggestive findings (including imaging or histopathology findings of amyloidosis) and a heterozygous pathogenic (or likely pathogenic) variant in *TTR* identified by molecular genetic testing; **AND**
- Used for the treatment of polyneuropathy as demonstrated by at least TWO of the following criteria:
  - Subjective member symptoms are suggestive of neuropathy
  - Abnormal nerve conduction studies are consistent with polyneuropathy
  - Abnormal neurological examination is suggestive of neuropathy; **AND**
- Peripheral neuropathy is attributed to hATTR and other causes of neuropathy have been excluded; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council (MRC) muscle strength, etc.); **AND**

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- Member has not been the recipient of an orthotopic liver transplant (OLT)

Cardiomyopathy of Wild Type or Hereditary Transthyretin-Mediated Amyloidosis (ATTR-CM) † Φ [1,9]

- Member has evidence of cardiac involvement by echocardiography with an end-diastolic interventricular septal wall thickness > 12 mm; **AND**
- Member has a definitive diagnosis of Wild Type or Hereditary ATTR-CM as confirmed by laboratory testing (e.g., stannous pyrophosphate [PYP] scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing [TTR genotyping]); **AND**
  - Member has a medical history of heart failure which required at least 1 prior hospitalization; **OR**
  - Member has clinical evidence of heart failure (with or without hospitalization) manifested by signs and symptoms of volume overload or elevated intracardiac pressure (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) which requires/required treatment with a diuretic; **AND**
- Member has baseline New York Heart Association (NYHA) Class I or II heart failure OR Class III heart failure that is not considered high risk (i.e., excludes members with NYHA high risk Class III disease and Class IV disease); **AND**
- Member has a baseline 6-minute walk-test (6MWT) distance of ≥150 meters

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s) **Φ** Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: ocular symptoms related to vitamin A deficiency (e.g., night blindness), etc.; **AND**

Polyneuropathy due to Hereditary Transthyretin-Mediated (hATTR) Amyloidosis [1,5-8]

- Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
  - Signs and symptoms of neuropathy
  - MRC muscle strength

Cardiomyopathy of Wild Type or Hereditary Transthyretin-Mediated Amyloidosis (ATTR-CM) [1,9]

- Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
  - Frequency of cardiovascular-related hospitalizations or urgent heart failure visits

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- Total distance walked during 6-minute walk test (6MWT)

V. Dosage/Administration [1]

Indication	Dose
All Indications	• The recommended dosage of Amvuttra is 25 mg administered by subcutaneous injection once every 3 months. • ***Note:*** Amvuttra should be administered by a healthcare professional.

VI. Billing Code/Availability Information

HCPCS Code:

- J0225 – Injection, vutrisiran, 1 mg; 1 billable unit = 1 mg

NDC:

- Amvuttra 25 mg/0.5 mL single-dose prefilled syringe: 71336-1003-xx

VII. References

1. Amvuttra [package insert]. Cambridge, MA; Alnylam Pharmaceuticals, Inc., March 2025. Accessed July 2026.
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5. Sekijima Y, Nakamura K. Hereditary Transthyretin Amyloidosis. In: Adam MP, Feldman J, Mirzaa G, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993–2024. Initial Posting: November 5, 2001; Last Update: May 30, 2024. Accessed June 01, 2026. https://www.ncbi.nlm.nih.gov/books/NBK1194/.
6. Luigetti M, Romano A, DiPaolantonio A, et al. Diagnosis and Treatment of Hereditary Transthyretin Amyloidosis (hATTR) Polyneuropathy: Current Perspectives on Improving Patient Care. Ther Clin Risk Manag. 2020; 16: 109–123.Published online 2020 Feb 21. doi: 10.2147/TCRM.S219979
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9. Fontana M, Berk JL, Gillmore JD, et al; HELIOS-B Trial Investigators and Collaborators. Vutrisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy. N Engl J Med. 2025 Jan 2;392(1):33-44. doi: 10.1056/NEJMoa2409134. Epub 2024 Aug 30. PMID: 39213194.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E85.1	Neuropathic heredofamilial amyloidosis
E85.4	Organ-limited amyloidosis
E85.82	Wild-type transthyretin-related (ATTR) amyloidosis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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