PHARMACY POLICY STATEMENT
TRICARE

DRUG NAME	Amvuttra (vutrisiran)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Amvuttra, approved by the FDA in 2022, is a transthyretin-directed small interfering RNA indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. It is also indicated for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visit.
Amvuttra is an RNA interference (RNAi) drug that causes degradation of mutant and wild-type TTR mRNA, which results in a reduction of serum TTR protein and TTR protein deposits in tissues by delivering the vutisiran small interfering RNA (siRNA) to hepatocytes where TTR protein is synthesized.
hATTR is a rare and progressive inherited disorder where misfolded TTR accumulates as amyloid fibrils in the body. In polyneuropathy of hATTR (hATTR-PN), these fibrils deposit in the peripheral nerves which leads to pain, muscle weakness, and autonomic dysfunction.
In the cardiomyopathy form of ATTR (ATTR-CM), the amyloid accumulates in the myocardium, resulting in heart failure. The hereditary form of ATTR (hATTR) is caused by a mutation in the TTR gene, whereas wild type ATTR (ATTRwt) is associated with aging.

Amvuttra (vutrisiran) will be considered for coverage when the following criteria are met:

Hereditary Transthyretin Amyloidosis (hATTR Amyloidosis): Polyneuropathy

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of hATTR amyloidosis with documentation of a transthyretin (TTR) mutation confirmed by genetic testing; AND
4. Member has signs/symptoms of polyneuropathy; AND
5. Member has a polyneuropathy disability (PND) score of IIIb or less (i.e., member is not wheelchair-bound or bedridden); AND
6. Amvuttra will NOT be used in combination with another TTR silencer or a TTR stabilizer .
7. **Dosage allowed/Quantity limit:** 25 mg subQ every 3 months, administered by a healthcare professional. (QL: 1 syringe per 84 days)

If all the above requirements are met, the medication will be approved for 9 months.

For **reauthorization**:
1. Chart notes must include documentation of positive clinical response to therapy such as improvement or stabilization of neuropathy impairment, gait speed, nutritional status, disability, or quality of life compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Transthyretin Amyloid Cardiomyopathy (ATTR-CM)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a cardiologist; AND
3. Member has a documented diagnosis of ATTR-CM confirmed by one of the following (a or b):
   a) Endomyocardial biopsy showing amyloidosis, with confirmatory TTR amyloid typing (by immunohistochemistry and/or mass spectrometry)
   b) Both of the following:
      i) Positive technetium-99m (99mTc) bone scintigraphy scan (Perugini grade 2 or 3 myocardial uptake), and
      ii) Absence of monoclonal light chains (based on both immunofixation electrophoresis (IFE) of serum and urine, and serum free light chain (sFLC) analysis); AND
4. Member has left ventricular (LV) wall thickness ≥ 12 mm (measured by ECHO or CMR); AND
5. Member has a history of heart failure (HF) with at least one of the following:
   a) At least 1 previous hospitalization for HF
   b) Signs and symptoms of volume overload or elevated intracardiac pressures
   c) HF symptoms that resulted in diuretic treatment; AND
6. Member has New York Heart Association (NYHA) Class I-III (not class IV) symptoms due to ATTR-CM; AND
7. Amvuttra will NOT be used in combination with another TTR silencer or a TTR stabilizer.
8. **Dosage allowed/Quantity limit:** 25 mg subQ every 3 months, administered by a healthcare professional. (QL: 1 syringe per 84 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document a positive clinical response to therapy such as stabilized or improved functional capacity (e.g., distance walked on 6-minute walk test [6MWT]), reduced cardiovascular-related hospitalizations, or improved quality of life score.

If all the above requirements are met, the medication will be approved for an additional 12 months.

TRICARE Prime® Demo by CareSource Military & Veterans™considers Amvuttra (vutrisiran) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/01/2022	New policy for Amvuttra created.
04/19/2023	Added “or stabilization” to the renewal section.

03/26/2025	hATTR-PN: Updated references. Removed liver transplant exclusion (Karam 2024, Alcantara 2022). Added criteria for new indication ATTR-CM.

References:

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