

<b>Policy Name:</b>	<b>Amvuttra (vutrisiran)</b>	<b>Policy #:</b>	<b>3151P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Amvuttra (vutrisiran).

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Amvuttra (vutrisiran) under the specialty medical benefit, when the following criteria have been met.

## Criteria

### 1. Coverage Criteria

- 1.1 Diagnosis of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis
- 1.2 Documentation that the patient has a pathogenic TTR mutation
- 1.3 Age 18 years of age or older
- 1.4 Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction)
- 1.5 One of the following:
  - Patient has a baseline polyneuropathy disability (PND) score IIIb
  - Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- 1.6 Prescribed by or with a neurologist (nervous system doctor)

### 2. Exclusion Criteria

- 2.1 Members also taking Tegsedi or Onpattro (coverage will not be approved for duplications of therapy)

### 3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Reapproval: 12 months with documentation that the patient has experienced a positive clinical response to Amvuttra (e.g., improved neurologic impairment, motor function, cardiac function, quality of life assessment, serum TTR levels, etc.)

## References

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



## Pharmacy Drug Policy & Procedure

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DISCLAIMER This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage