

Policy Name:	Amvuttra (vutrisiran)	Policy #:	3151P
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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 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 any other systemic therapy for hATTR (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: Alynham 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.

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