HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

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

Amvuttra is a transthyretin-directed small interfering RNA indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. It 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. In the HELIOS-A study, Amvuttra met the primary efficacy endpoint of change from baseline to Month 9 in modified Neuropathy Impairment Score +7 (mNIS+7), an objective assessment of neuropathy.
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. Onpattro, which has the same mechanism as Amvuttra, and Tegsedi are two other drugs approved for the treatment of hATTR-PN. Amvuttra has the advantage of less frequent dosing than Onpattro.

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. Member has NOT had a liver transplant; AND
7. Amvuttra is NOT being used in combination with another hATTR drug (e.g., Onpattro, Tegsedi, Vyndaqel, Vyndamax).
8. **Dosage allowed/Quantity limit:** 25 mg subQ every 3 months, administered by a healthcare professional. (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.

HAP CareSource 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.

References:

1. Amvuttra. Prescribing information. Alnylam Pharmaceuticals, Inc.; 2022.
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 [published online ahead of print, 2022 Jul 23]. *Amyloid*. 2022;1-9. doi:10.1080/13506129.2022.2091985
3. Ando Y, Adams D, Benson MD, et al. Guidelines and new directions in the therapy and monitoring of ATTRv amyloidosis [published online ahead of print, 2022 Jun 2]. *Amyloid*. 2022;1-13. doi:10.1080/13506129.2022.2052838
4. Sekijima Y. Hereditary Transthyretin Amyloidosis. 2001 Nov 5 [Updated 2021 Jun 17]. In: Adam MP, Mirzaa GM, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1194/
5. Dyck PJB, González-Duarte A, Obici L, et al. Development of measures of polyneuropathy impairment in hATTR amyloidosis: From NIS to mNIS + 7. *J Neurol Sci*. 2019;405:116424. doi:10.1016/j.jns.2019.116424
6. Adams D, Ando Y, Beirão JM, et al. Expert consensus recommendations to improve diagnosis of ATTR amyloidosis with polyneuropathy. *J Neurol*. 2021;268(6):2109-2122. doi:10.1007/s00415-019-09688-0

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