Medical Policy

Amvuttra (vutrisiran)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_130
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Amvuttra (vutrisiran) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage will be provided for six months and may be renewed.

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

- 25 mg every 3 months

Initial Criteria

1. Patient is at least 18 years of age; **AND**
2. Patient is receiving supplementation with vitamin A at the recommended daily allowance; **AND**
3. Amvuttra will not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen, tafamidis, patisiran, etc.); **AND**
4. Patient has a definitive diagnosis of hATTR amyloidosis/FAP as documented by amyloid deposition on tissue biopsy and identification of a pathogenic TTR variant using molecular genetic testing; **AND**
5. Amvuttra will be used for the treatment of polyneuropathy as demonstrated by at least TWO of the following criteria:
    a. Subjective patient symptoms are suggestive of neuropathy
    b. Abnormal nerve conduction studies are consistent with polyneuropathy
    c. Abnormal neurological examination is suggestive of neuropathy; **AND**
6. Patient's peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; **AND**
7. Patient's baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council (MRC) muscle strength, etc.); **AND**
8. Patient has not been the recipient of an orthotopic liver transplant (OLT).

Renewal Criteria

1. Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include ocular symptoms related to hypovitaminosis A, etc.; **AND**
3. Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
    a. Signs and symptoms of neuropathy
    b. MRC muscle strength

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

CODING

Applicable NDC Codes	
71336-1003 -01	Amvuttra 25 mg/0.5 mL single-dose prefilled syringe

Applicable Procedure Code	
J3490	Unclassified drugs

Applicable ICD-10 Codes	
E85.1	Neuropathic heredofamilial amyloidosis

EVIDENCE BASED REFERENCES

1. Amvuttra [package insert]. Cambridge, MA; Alnylam Pharmaceuticals, Inc., June 2022. Accessed October 2022.

POLICY HISTORY

Revision History	Month Day, Year	Updates
Original Effective Date	NOVEMBER 8, 2022	
Revision	MARCH 1, 2023	Adopted by MA UMC
P&T Committee Endorsement	NOVEMBER 8, 2022	
Revision	01/01/2024	Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan