amvuttra (vutrisiran) injection 25 mg/0.5 mL

Prior Authorization Considerations for AMVUTTRA® (vutrisiran)

Payers may require documentation of medical necessity criteria, drug information, and other information or documentation to support prior authorization and coverage decision making for AMVUTTRA. Prior authorization criteria vary by plan, and this information is provided only as a guide to support payer interaction and reimbursement. Providers should always check with their Medicare contractor, state Medicaid program, and private payers to confirm coverage requirements.

Note: This document is intended for informational purposes only and does not guarantee coverage. Medical chart documentation should be based on each patient's individual history, prior testing results, clinical condition, and actions performed by the clinician and other parties.

Prior Authorization Checklist

- ☐ Specific payer preauthorization/prior authorization form
- ☐ Letter of medical necessity
- ☐ Clinical documentation and chart notes
- ☐ AMVUTTRA Prescribing Information
- ☐ Relevant literature, including published standards of care

Examples of Documentation Requirements

- Confirmation of diagnosis by genetic testing, tissue biopsy testing, and/or diagnostic imaging as appropriate
- Documentation of symptomatic disease and related assessments
- Patient medical history including prior treatments
- Prescribed by, or in consultation with physician specializing in the treatment of amyloidosis

Ambulatory Status Assessments for hATTR Amyloidosis

POLYNEUROPATHY DISABILITY (PND) SCORE

Modified PND scoring system as described by Yamamoto et al., to assess the polyneuropathy in patients with hATTR amyloidosis.[1]

- 0 – no symptoms
- I – sensory disturbances but preserved walking capability
- II – impaired walking capacity but ability to walk without a stick or crutches
- IIIa – walking with the help of one stick or crutch
- IIIb – walking with the help of two sticks or crutches
- IV – confined to a wheelchair or bedridden

FAMILIAL AMYLOID POLYNEUROPATHY (FAP) STAGE

Clinical staging system as described by Coutinho et al., according to sensory and motor neuropathy progression.[2]

- 0 – no symptoms
- I – unimpaired ambulation; mostly mild sensory and motor neuropathy in lower limbs
- II – assistance with ambulation required; mostly moderate impairment progression to the lower limbs, upper limbs and trunk
- III – wheelchair-bound or bedridden; severe sensory and motor involvement of all limbs

NEUROPATHY IMPAIRMENT SCORE (NIS)

A composite score of neurologic impairments (weakness, reflex loss, and sensory loss) using standard assessment of muscle weakness and groups of muscles, reflexes, and sensory modalities at specific sites on both sides of the body.[3]

Please see Indications and Important Safety Information **on page 2 and accompanying full** Prescribing Information

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Indications and Important Safety Information

INDICATIONS

AMVUTTRA® (vutrisiran) is 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 visits.
- polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) in adults.

IMPORTANT SAFETY INFORMATION

Reduced Serum Vitamin A Levels and Recommended Supplementation

AMVUTTRA treatment leads to a decrease in serum vitamin A levels.

Supplementation at the recommended daily allowance (RDA) of vitamin A is advised for patients taking AMVUTTRA. Higher doses than the RDA should not be given to try to achieve normal serum vitamin A levels during treatment with AMVUTTRA, as serum vitamin A levels do not reflect the total vitamin A in the body.

Patients should be referred to an ophthalmologist if they develop ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness).

Adverse Reactions

In a study of patients with hATTR-PN, the most common adverse reactions that occurred in patients treated with AMVUTTRA were pain in extremity (15%), arthralgia (11%), dyspnea (7%), and vitamin A decreased (7%).

In a study of patients with ATTR-CM, no new safety issues were identified.

For additional information about AMVUTTRA, please see the full Prescribing Information.

References: 1. Yamamoto S, Wilczek HE, Nowak G, et al. Am J Transplant. 2007;7(11):2597-2604. 2. Coutinho P, Martins da Silva A, Lopes Lima J, et al. Excerpta Medica.1980:88-98. 3. Dyck PJB, González-Duarte A, Obici L, et al. J Neurol Sci. 2019;405:116424.

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