Vutrisiran (AMVUTTRA) for Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Criteria for Use June 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive vutrisiran.

- ☐ Heart failure not related to transthyretin-mediated amyloidosis (ATTR) (e.g., heart failure secondary to ischemic heart disease)
- ☐ Patient receiving concomitant therapy for ATTR (e.g., eplontersen, inotersen, patisiran, tafamidis, acoramidis)^1
- ☐ End stage heart disease and anticipated survival < 1 year

Inclusion Criteria

All of the following criteria must be met.

- ☐ Provider is a VA or VA Community Care cardiologist or locally designated ATTR-CM provider
- ☐ Diagnosis of wild type or hereditary TTR genotype ATTR-CM based on 1) endomyocardial biopsy OR 2) echo/MRI suggestive of amyloidosis confirmed with radionuclide imaging (e.g., technetium pyrophosphate [Tc99-PYP] scintigraphy)
- ☐ Assessment of monoclonal protein screen for and exclusion of light chain (AL) amyloidosis^2
- ☐ History of symptomatic heart failure^3
- ☐ Supplementation of the recommended daily allowance of vitamin A is advised for patients taking vutrisiran^4
- ☐ Discussion with patient/caregiver/family member regarding realistic treatment expectations and discontinuation should be documented

Additional Inclusion Criteria

- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment

^1 Combination disease modifying ATTR-CM therapy has not been specifically studied or determined to be superior to single agent therapy.

^2 In rare cases, ATTR-CM and AL amyloidosis may coexist; these cases should be adjudicated locally.

^3 At least one hospitalization for heart failure OR clinical evidence of heart failure manifested by signs and symptoms of volume overload or elevated intracardiac pressures

^4 Patients should be referred to eye clinic if they develop ocular symptoms suggestive of vitamin A deficiency (e.g., night blindness).

Prepared: June 2025. Contact: Lisa Longo, Pharm.D., BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)