

vutrisiran (Amvuttra)

Commercial Medical Benefit Drug Policy

Place of Service

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Drug Details

USP Category: CENTRAL NERVOUS SYSTEM AGENTS

Mechanism of Action: A-transthyretin-directed small interfering RNA.

HCPCS:

J0225:Injection, vutrisiran, 1 mg

How Supplied:

25 mg/0.5 mL solution in a single-dose 1-mL prefilled syringe

Condition(s) listed in policy *(see coverage criteria for details)*

- Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM)
- Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR-PN)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is receiving their first infusion of this drug or is being re-initiated on this drug after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM)

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication (18 years of age and older)
2. Prescribed by or in consultation with a relevant specialist or physician experienced in the treatment of ATTR amyloidosis
3. Presence of transthyretin (TTR) confirmed by a pathogenic TTR mutation or TTR identified by immunohistochemistry, scintigraphy, or mass spectrometry
4. Not being used in combination with another TTR silencer [e.g., Onpattro, Wainua] or TTR stabilizer [tafamidis (Vyndaqel, Vyndamax), acoramidis (Attruby)]

Covered Doses:

Up to 25 mg given subcutaneously once every 3 months

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

E85.4, E85.82

Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR-PN)

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication (18 years of age or older)
2. Prescribed by or in consultation with a relevant specialist or physician experienced in the treatment of ATTR amyloidosis

3. Diagnosis of hATTR with polyneuropathy confirmed by a pathogenic TTR mutation
4. Not being used in combination with another TTR silencer [e.g., Onpattro, Wainua] or TTR stabilizer [tafamidis (Vyndaqel, Vyndamax), acoramidis (Attruby)]

Covered Doses:

Up to 25 mg given subcutaneously once every 3 months

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

E85.1

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. Amvuttra (vutrisiran) Prescribing Information. Alnylam Pharmaceuticals, Inc., Cambridge, MA: 03/2025.
3. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- Clarify specialist requirement to include all relevant specialists or physicians experienced in the treatment of ATTR amyloidosis

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*