vutrisiran (Amvuttra)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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 spectometry
4. Not being used in combination with another TTR silencer [e.g., Onpattro, Wainua] or TTR stabilizer [tafamidis (Vyndaqel, Vyndamax), acoramidis (Attruby)]

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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: 3Q2026
Changes from previous policy version:
- No clinical changes following annual review.

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