ATRIO HEALTH PLANS

Amvuttra

Amvuttra (vutrisiran) J0025

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Hereditary Transthyretin-Mediated Amyloidosis with Polyneuropathy (hATTR-PN)
- ☐ Patient is 18 years of age or older AND
- ☐ Documentation of pathogenic TTR gene variant via genetic testing from CLIA-certified laboratory AND
- ☐ Presence of symptomatic polyneuropathy (e.g., Neuropathy Impairment Score between 5-130, Polyneuropathy Disability Score ≤ IIIb) AND
- ☐ Prescribed by or in consultation with neurologist, geneticist, or amyloidosis specialist AND
- ☐ Patient has not received liver transplant

☐ ATTR Cardiomyopathy (wild-type or hereditary)
- ☐ Patient is 18 years of age or older AND
- ☐ Echocardiogram or cardiac MRI showing ventricular wall thickening (≥12 mm) in absence of aortic valve disease or hypertension AND
- ☐ Confirmation of ATTR amyloidosis via either:
  - ☐ Grade 2 or 3 cardiac uptake on 99mTc-PYP/DPD scintigraphy with negative serum/urine monoclonal protein studies OR
  - ☐ Endomyocardial biopsy demonstrating TTR amyloid OR

☐ TTR gene sequencing showing pathogenic variant (for hereditary) AND
☐ Presence of heart failure symptoms (NYHA class I-III) AND
☐ Prescribed by or in consultation with cardiologist experienced in amyloidosis

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)
☐ Patient had an **adequate response** or **significant improvement** while on this medication.
☐ Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Amvuttra Prior Authorization

Drug Name(s):

AMVUTTRA **VUTRISIRAN**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Neurologist, Geneticist, or other amyloidosis related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Amvuttra

- Transthyretin amyloid cardiomyopathy, Wild-type or hereditary.
- Transthyretin-related familial amyloid polyneuropathy

Off-Label Uses:

N/A

Age Restrictions:

Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/C1FFDC/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/10BB28/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933618&contentSetId=100&title=Vutrisiran&servicesTitle=Vutrisiran&brandName=Amvuttra&UserMdxSearchTerm=Amvuttra#