# SENTARA HEALTH PLANS

## MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

**Directions:** **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

**For Medicare Members:** Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

**Drug Requested: Amvuttra™** (vutrisiran) **SQ (J0225) MEDICAL**

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

**Member Name:** _____

**Member Sentara #:** _____ **Date of Birth:** _____

**Prescriber Name:** _____

**Prescriber Signature:** _____ **Date:** _____

**Office Contact Name:** _____

**Phone Number:** _____ **Fax Number:** _____

**NPI #:** _____

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

**Drug Form/Strength:** _____

**Dosing Schedule:** _____ **Length of Therapy:** _____

**Diagnosis:** _____ **ICD Code, if applicable:** _____

**Weight (if applicable):** _____ **Date weight obtained:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

**Recommended Dosage:**

- 25 mg administered by subcutaneous injection once every 3 months
  - 25 mg/0.5 mL prefilled syringe = 25 billable units; 25 billable units every 3 months

**Quantity Limit:** 25 mg (one prefilled syringe) every 3 months (4 doses per year)

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**CLINICAL CRITERIA:** Check below all that apply. **All criteria must be met for approval**. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

## ❑ Diagnosis: Transthyretin-Mediated Polyneuropathy

**Initial Authorization: 6 months**

- ❑ Medication is prescribed by or in consultation with a neurologist
- ❑ Member is 18 years of age or older
- ❑ Member must have a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis polyneuropathy or familial amyloid polyneuropathy (FAP) confirmed by **BOTH** of the following:
  - ❑ Documented genetic mutation of a pathogenic *TTR* variant
  - ❑ Confirmation of amyloid deposits on tissue biopsy
- ❑ Member must have documentation of the following:
  - ❑ Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability)
  - ❑ Clinical exam findings of abnormal nerve conduction study or neurological examination results
- ❑ Member has **ONE** of the following:
  - ❑ A baseline polyneuropathy disability (PND) score ≤ IIIb
  - ❑ A baseline FAP Stage 1 or 2 (stage 1=ambulatory, stage 2=ambulatory with assistance)
- ❑ Member has **NOT** received a liver transplant
- ❑ Member has been instructed to take the recommended daily allowance of vitamin A

## ❑ Diagnosis: Transthyretin-Mediated Polyneuropathy

**Reauthorization: 6 months.** All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member has previously received treatment with requested medication
- ❑ Provider has submitted documentation to support **ONE** of the following:
  - ❑ Member continues to have a polyneuropathy disability (PND) score ≤ IIIb
  - ❑ Member continues to have a FAP Stage 1 or 2
- ❑ Member has experienced a positive clinical response to the medication confirmed via chart notes (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression)

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## ❑ Diagnosis: Transthyretin-Mediated Cardiomyopathy without Polyneuropathy

**Initial Authorization: 12 months**

- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with a cardiologist
- ❑ Member has echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis (i.e., with left ventricular wall thickness ≥ 12 mm) and a medical history of heart failure with at least **ONE** of the following:
  - ❑ At least **ONE (1)** prior hospitalization for heart failure
  - ❑ Signs and symptoms of volume overload or requires treatment with diuretics
- ❑ Member has New York Heart Association (NYHA) class I, II, or III heart failure **[NOTE:** If NYHA Class III heart failure, member must **NOT** be considered high risk (high risk defined as NT-proBNP > 3000 ng/L and eGFR <45 mL/min/1.73 $m^2$)] **(submit documentation)**
- ❑ Light chain amyloidosis has been ruled out through all three of the following tests: serum free light chain assay (sFLC), serum and urine protein immunofixation electrophoresis (SIFE, UIFE) **(submit documentation)**
- ❑ Member has a diagnosis of wild type or hereditary (variant) transthyretin amyloid cardiomyopathy (ATTR-CM) confirmed by **ONE** of the following **(submit documentation)**:
  - ❑ Cardiac tissue biopsy demonstrating histologic confirmation of transthyretin (TTR) amyloid deposits
  - ❑ Nuclear scintigraphy imaging (e.g., with Tc-PYP) showing grade 2 or 3 cardiac uptake
  - ❑ Genetic testing confirming a pathogenic transthyretin mutation (i.e.,Val122Ile)
- ❑ Member must meet **ONE** of the following:
  - ❑ Provider has submitted documentation of worsening progression despite treatment with **ONE** transthyretin stabilizer (Vyndamax®, Vyndaqel®, Attruby™) for at least 90 consecutive days, as shown by worsening signs and symptoms of heart failure, increase in NYHA class, hospitalizations for heart failure, or rate of decline in quality of life **(verified by chart notes and pharmacy paid claims MUST show adherence to therapy)**
  - ❑ Provider has submitted documentation to confirm member intolerance or contraindication to both tafamidis (Vyndamax® or Vyndaqel®) **AND** acoramidis (Attruby™)
- ❑ Member has at least **ONE** of the following baseline assessments of disease status **(submit documentation)**:

| | |
|---|---|
| ❑ Kansas City Cardiomyopathy Questionnaire score | ❑ 6-minute walk distance |
| ❑ Frequency of cardiovascular hospitalizations | ❑ Cardiac biomarkers (e.g., NT-proBNP) |

- ❑ Amvuttra will **NOT** be used in combination with another therapy targeting transthyretin (e.g., Attruby™, Vyndamax™, Vyndaqel®, Onpattro®, Wainua™)
- ❑ Member has been instructed to take the recommended daily allowance of vitamin A

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## ❑ Diagnosis: Transthyretin-Mediated Cardiomyopathy without Polyneuropathy

**Reauthorization: 12 months.** All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member continues to have NYHA Functional Class I, II, or III heart failure
- ❑ Amvuttra will **NOT** be used in combination with another therapy targeting transthyretin (e.g., Attruby™, Vyndamax™, Vyndaqel®, Onpattro®, Wainua™)
- ❑ Member has been observed to have a positive clinical response since the beginning of therapy as evidenced by disease stability, or mild progression, in any of the following **(submitted in documentation and charted in clinical notes)**:

| | |
|---|---|
| ❑ Kansas City Cardiomyopathy Questionnaire score | ❑ 6-minute walk distance |
| ❑ Frequency of cardiovascular hospitalizations | ❑ Cardiac biomarkers (e.g., NT-proBNP) |

## EXCLUSIONS – Therapy will NOT be approved if member has history of any of the following:

- Amvuttra is considered experimental, investigational, or unproven for **ANY** other use including the following:
  - History of liver transplant
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
  - New York Heart Association (NYHA) class IV heart failure
  - Sensorimotor or autonomic neuropathy not related to hereditary transthyretin amyloidosis (e.g., monoclonal gammopathy, autoimmune disease)
  - Cardiomyopathy not related to transthyretin amyloidosis
  - Concurrent use of Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), Attruby™ (acroramidis), Onpattro® (patisiran), Wainua™ (eplontersen), or diflunisal

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**Medication being provided by (check applicable box(es) below):**

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

***Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

***Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****



***Approved by Pharmacy and Therapeutics Committee:** ~~9/16/2022;~~ **5/22/2025**
**REVISED/UPDATED:** ~~6/7/2019;~~ ~~(Reformatted) 7/7/2019; 9/24/2019;~~ **6/11/2025**