SENTARA HEALTH PLANS

PHARMACY 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 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Transthyretin Stabilizers

Drug Requested:

❑ **Attruby™** (acoramidis)	❑ **Vyndamax™** (tafamidis)	❑ **Vyndaqel®** (tafamidis meglumine)

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 Name/Form/Strength: _____

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

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

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

Recommended Dosing & Quantity Limits:

Drug Name	Dosing	Quantity Limits
Attruby™ (acoramidis)	712 mg twice daily	4 tablets per day
Vyndamax™ (tafamidis)	61 mg once daily	1 capsule per day
Vyndaqel® (tafamidis meglumine)	80 mg once daily	4 capsules per day

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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.

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 **(submit chart notes)**
- ❑ 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 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)

- ❑ Requested medication will **NOT** be used in combination with another therapy targeting transthyretin (e.g., Attruby™, Vyndamax™, Vyndaqel®, Amvuttra™, Onpattro®, Wainua™)
- ❑ Member has **NOT** received a liver or heart transplant
- ❑ **Attruby™ requests**: Did the member participate in the ATTRibute-CM clinical trial? ❑ Yes ❑ No

Reauthorization: 12 months. Check below all that apply. All criteria must be met 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
- ❑ Requested medication will **NOT** be used in combination with another therapy targeting transthyretin (e.g., Attruby™, Vyndamax™, Vyndaqel®, Amvuttra™, Onpattro®, Wainua™)

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- ❑ 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)

Medication being provided by Specialty Pharmacy – Proprium Rx

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:** ~~9/20/2019;~~ **1/23/2025**
REVISED/REFORMATTED/UPDATED: ~~10/8/2019; 12/7/2020; 10/27/2023; 3/15/2024;~~**2/18/2025**