

AvMed

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 1-305-671-0200.** 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:

<input type="checkbox"/> Attruby™ (acoramidis)	<input type="checkbox"/> Vyndamax™ (tafamidis)	<input type="checkbox"/> Vyndaqel® (tafamidis meglumine)
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MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ 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:

<u>Drug Name</u>	<u>Dosing</u>	<u>Quantity Limits</u>
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 \geq 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**):

<input type="checkbox"/> Kansas City Cardiomyopathy Questionnaire score	<input type="checkbox"/> 6-minute walk distance
<input type="checkbox"/> Frequency of cardiovascular hospitalizations	<input type="checkbox"/> 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**):

<input type="checkbox"/> Kansas City Cardiomyopathy Questionnaire score	<input type="checkbox"/> 6-minute walk distance
<input type="checkbox"/> Frequency of cardiovascular hospitalizations	<input type="checkbox"/> 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.****