

SENTARA COMMUNITY PLAN (MEDICAID)

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.**

Drug Requested: (Select drug below)

Vyndaqel® (tafamidis meglumine)

Vyndamax™ (tafamidis)

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: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

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 – 6 months

1. Is the member 18 years of age or older? **AND** Yes No
2. Does the member have a definitive diagnosis of amyloid transthyretin (ATTR) amyloidosis as documented by amyloid deposition on tissue biopsy AND identification of a pathogenic TTR variant and/or TTR precursor using molecular genetic testing (e.g., immunohistochemical analysis, scintigraphy, or mass spectrometry)? **AND** Yes No

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3. Does the member have evidence of cardiac involvement as documented by echocardiography (ECG) with an end-diastolic interventricular septal wall thickness > 12 mm? **AND**
- Yes No
- Does the member have a history of heart failure (HF) which required ≥ 1 hospitalization? **OR**
 - Does the member have clinical evidence of HF, without a prior history of hospitalization for disease, manifested by signs or symptoms of volume overload or elevated cardiac pressure (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) which requires/required treatment with a diuretic? **AND**
- Yes No
4. Does the member have a baseline 6-minute walk test (6MWT) distance > 100 m? **AND**
- Yes No
5. Confirm the member does NOT have any of the following:
- New York Heart Association (NYHA) classification of III or IV; **AND**
 - Primary (light chain) amyloidosis; **AND**
 - Prior liver transplant; **AND**
 - Implanted cardiac mechanical-assist device (implanted cardioverter defibrillator, pacemaker, left-ventricular assist device, etc); **AND**
- Yes No
6. Confirm that tafamidis is NOT being used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen, patisiran, etc.). **AND**
- Yes No

Reauthorization Approval – 1 year. 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.

7. Does the member continue to meet the above criteria? **AND**
- Yes No
8. Does the member demonstrate absence of unacceptable toxicity from the drug? **AND**
- Yes No
9. Does the member demonstrate disease response compared to pre-treatment baseline as evidenced by:
- Decreased frequency of cardiovascular-related hospitalizations; **OR**
 - Improvement in the total distance walked during the 6MWT as compared to baseline?
- Yes No

Medication being provided by a Specialty Pharmacy - PropriumRx

****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.