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.**

Drug Requested: (select one from below)

❑ **Vyndaqel®** (tafamidis meglumine)	❑ **Vyndamax®** (tafamidis)

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:** _____

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:** _____

❑ **INITIAL REQUEST - 6 MONTHS** ❑ **REAUTHORIZATION - 12 MONTHS**

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.

❑ Member is 18 years of age and older

AND

❑ Prescribed by or in consultation with a Cardiologist

AND

(Continued on next page)

- ❑ Member must meet **ONE** of the following:
  - ❑ Member has presence of clinical signs and symptoms of heart failure without a prior history of hospitalization for disease, manifested by signs or symptoms of volume overload or elevated cardiac pressure (e.g., dyspnea or signs of pulmonary congestion on x-ray or auscultation, peripheral edema, elevated jugular venous pressure) which requires/required treatment with a diuretic for improvement.
  - ❑ Member has a history of heart failure, with at least one prior hospitalization for heart failure

AND

- ❑ Member has New York Heart Association (NYHA) class I or II heart failure (excludes patients with NYHA class III and IV symptoms) **(chart notes must be submitted)**

AND

- ❑ Light chain amyloidosis has been ruled out through serum free light chain assay with serum and urine protein electrophoresis and immunofixation

AND

- ❑ Member has a diagnosis of wild type or hereditary ATTR-CM confirmed by the following **(supportive documentation from medical records must be attached with this request)**:
  - ❑ Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis (i.e., with an end diastolic interventricular septal wall thickness of > 12 mm)

AND

  - ❑ Member must meet **ONE** of the following:
    - ❑ Cardiac **OR** non-cardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits
    - ❑ Nuclear scintigraphy imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake
    - ❑ Genetic testing confirming a TTR mutation (i.e.,Val122Ile)

AND

- ❑ Will the requested medication be used in combination with Tegsedi®, Amvuttra® or Onpattro®?
  - ❑ Yes ❑ No ****Please note: If yes, the requested medication will NOT be approved****
- ❑ Has the member had a liver or heart transplant?
  - ❑ Yes ❑ No ****Please note: If yes, the requested medication will NOT be approved****

Reauthorization: 12 months. Authorization of **12 months** may be granted for continued treatment when **ALL** the following are met. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) **must** be provided or request may be denied.

- ❑ Prescribed by or in consultation with a Cardiologist

AND

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- ❑ Member must continue to have NYHA Functional Class I or II heart failure

AND

- ❑ Prescribed medication will not be used in combination with Tegsedi®, Amvuttra® or Onpattro®

AND

- ❑ Documentation of a positive clinical response to therapy with at least **ONE** of the following:
  - ❑ Improvement in distance walked on 6-minute walk test from baseline **(please include baseline/current)**
  - ❑ Decrease in cardiovascular related hospitalizations
  - ❑ Improvement in cardiac biomarkers (i.e., NT-proBNP levels) **(please submit baseline/current labs)**
  - ❑ Improvement in the rate of decline in quality of life via the Kansas City Cardiomyopathy questionnaire-overall summary score (KCCQ-OS) **(please include if applicable)**

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.