

Prior Authorization Criteria  
**Selective Transthyretin (TTR) Stabilizers**

All requests for Selective Transthyretin (TTR) stabilizers require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Selective Transthyretin (TTR) stabilizers include: Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis) and Amvuttra (vutrisiran).

Coverage may be provided with a diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) and the following criteria is met:

- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- The diagnosis is confirmed by presence of amyloid deposits on biopsy analysis from cardiac or non-cardiac sites (e.g., fat aspirate, gastrointestinal sites, salivary glands, bone marrow) or by technetium-labeled bone scintigraphy tracing
- Cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (MRI) (e.g., end-diastolic interventricular septal wall thickness equal to or exceeding 12 mm)
- For members with hereditary ATTR-CM, presence of a mutation of the TTR gene was confirmed
- For members with wild type ATTR-CM, presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, scintigraphy, or mass spectrometry
- The member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)
- Member has a New York Heart Association Class I, II or III heart failure
- The member is not being treated with more than 1 selective transthyretin (TTR) stabilizer at a time.
- Must be prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
- Member does not have a history of liver or heart transplantation
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Documentation confirming the member demonstrates a beneficial response to treatment (e.g., improvement on the 6-minute walk test, the Kansas City Cardiomyopathy Questionnaire–Overall Summary (KCCQ-OS) score, cardiovascular-related hospitalizations, NYHA classification of heart failure, left ventricular stroke volume, NT-proBNP level)
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or



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peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed.  
These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

**SELECTIVE TRANSTHYRETIN (TTR) STABILIZERS  
PRIOR AUTHORIZATION FORM- PAGE 1 of 2**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (800) 392-1147 Mon – Fri 8:30am to 5:00pm

**PROVIDER INFORMATION**

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

**MEMBER INFORMATION**

Member Name:	DOB:
Member ID:	Member weight: Height:

**REQUESTED DRUG INFORMATION**

Medication:	Strength:
Directions:	Quantity: Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	

**Billing Information**

This medication will be billed: <input type="checkbox"/> at a pharmacy <b>OR</b> <input type="checkbox"/> medically, JCODE: _____
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

**Place of Service Information**

Name:	NPI:
Address:	Phone:

**MEDICAL HISTORY (Complete for ALL requests)**

Diagnosis: ☐ Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM)  
☐ Other: \_\_\_\_\_ ICD-10 Code: \_\_\_\_\_

Has the diagnosis been confirmed by presence of amyloid deposits on biopsy analysis from cardiac or non-cardiac sites (e.g., fat aspirate, gastrointestinal sites, salivary glands, bone marrow) or by technetium-labeled bone scintigraphy tracing?  
☐ Yes ☐ No

Has cardiac involvement been confirmed by echocardiography or cardiac magnetic resonance imaging? ☐ Yes ☐ No

For members with hereditary ATTR-CM, has the presence of a TTR gene mutation been confirmed? ☐ Yes ☐ No

For members with wild type ATTR-CM, has the presence of transthyretin precursor proteins been confirmed by immunohistochemical analysis, scintigraphy, or mass spectrometry? ☐ Yes ☐ No

Does the member exhibit clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)? ☐ Yes ☐ No

Does the member have a New York Heart Association Class I, II or III heart failure? ☐ Yes ☐ No

The member is not being treated with more than 1 selective transthyretin stabilizer? ☐ Yes ☐ No

Does the member have a history of liver or heart transplantation? (for requests for Vyndaqel and Vyndamax) ☐ Yes ☐ No

Is the medication being prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis? ☐ Yes ☐ No

**CURRENT or PREVIOUS THERAPY**

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)



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**SELECTIVE TRANSTHYRETIN (TTR) STABILIZERS  
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2**

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If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (800) 392-1147 Mon – Fri 8:30am to 5:00pm

**MEMBER INFORMATION**

Member Name:	DOB:	
Member ID:	Member weight:	Height:

**REAUTHORIZATION**

Is there documentation confirming the member has demonstrated a beneficial response to treatment (e.g., improvement on the 6-minute walk test, Kansas City Cardiomyopathy Questionnaire–Overall Summary (KCCQ-OS) score, cardiovascular-related hospitalizations, NYHA classification of heart failure, left ventricular stroke volume, NT-proBNP level)? ☐ Yes ☐ No

**Prescribing Provider Signature**

**Date**