Prior Authorization Criteria

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis)

All requests for Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

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 18 years of age or older
- 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 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 will not receive Vyndaqel or Vyndamax in combination with either of the following
    - Tetramer stabilizers (e.g. diflunisal)
- 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

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.

HIGHMARK WHOLECARE

Updated: 08/2023
PARP Approved: 09/2023

VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis)
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? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ 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

Is the member receiving Vyndaqel or Vyndamax in combination with tetramer stabilizers (e.g. diflunisal)? ☐ Yes ☐ No

Does the member have a history of liver or heart transplantation? ☐ 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)

*** *continued on next page****

VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 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

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date