Gateway Health℠ It's Wholecare.

Updated: 07/2020
PARP Approved: 09/2020

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.

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VYNDAQEL (TAFAMIDIS MEGLUMINE) and VYNDAMAX (TAFAMIDIS) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a 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)

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VYNDAQEL (TAFAMIDIS MEGLUMINE) and VYNDAMAX (TAFAMIDIS)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

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