Harvard Pilgrim Health Care | TUFTS Health Plan

# Pharmacy Medical Necessity Guidelines: **Tafamidis Products: Vyndamax, Vyndaqel**

*Effective: April 14, 2026*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration – Approved Indications**

**Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine)** are transthyretin stabilizers indicated for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of Vyndamax or Vyndagel for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of wild type or hereditary (variant) transthyretin amyloid cardiomyopathy, confirmed by one (1) of the following:
    a. Cardiac scintigraphy with technetium-99m-labeled bone-seeking
    b. Endomyocardial biopsy
    c. Genetic testing

**AND**

2. Documentation demonstrating the absence of monoclonal protein in serum and urine, obtained through laboratory work, to rule out light chain amyloidosis cardiomyopathy

**AND**

3. Documentation of diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) demonstrating cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum)

**AND**

4. The patient is at least 18 years of age

**AND**

5. Prescribed by or in consultation with a cardiologist

**AND**

6. Documentation the patient has New York Heart Association (NYHA) functional class I, II, or III of heart failure

**AND**

7. Documentation of **one (1)** of the following:
    a. The patient has not had a prior cardiac or liver transplant
    b. Evidence of amyloid deposits post cardiac or liver transplantation

**AND**

8. Documentation the requested medication will not be used concomitantly with another medication indicated for the management of cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (e.g., Amvuttra, Onpattro, Tegsedi)

Reauthorization Criteria

1. Documented diagnosis of wild type or hereditary (variant) transthyretin amyloid cardiomyopathy

**AND**

2. Documentation demonstrating the absence of monoclonal protein in serum and urine, obtained through laboratory work, to rule out light chain amyloidosis cardiomyopathy

**AND**

3. Documentation of diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) demonstrating cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum)

**AND**

4. The patient is at least 18 years of age

**AND**

5. Prescribed by or in consultation with a cardiologist

**AND**

6. Documentation the Patient has New York Heart Association (NYHA) functional class I, II, or III of heart failure

**AND**

7. Documentation of **one (1)** of the following:
    a. The patient has not had a prior cardiac or liver transplant
    b. Evidence of amyloid deposits post cardiac or liver transplantation

**AND**

8. Documentation the requested medication will not be used concomitantly with another medication indicated for the management of cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (e.g., Amvuttra, Onpattro, Tegsedi)

**AND**

9. Documentation the patient has experienced a positive therapeutic response as evidenced by **one (1)** of the following:
    a. Improvement in the distance walked on the 6-minute walk test (6MWT) as compared to baseline
    b. Decreased number of cardiovascular-related hospitalizations
    c. Improvement in Kansas City Cardiomyopathy Questionnaire & Overall Summary (KCCQ-OS) score
    d. Clinical improvement in symptoms or slowing of disease progression

## Limitations

1. Initial coverage of a Tafamidis Product will be authorized for six (6) months. Reauthorization of a Tafamidis Product will be provided for 12-month intervals,
2. Members new to the plan stable on a Tafamidis Product should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

## Codes

None

## References


1. Gertz MA, et al. Diagnosis, prognosis, and therapy of transthyretin amyloidosis. J Amer Coll of Cardiology. 2015 Dec;66(21) 2451-66.
2. Mauer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018;379(11):1007-16.
3. National Institute of Health and Care Excellence. Tafamidis for treating transthyretin amyloid cardiomyopathy [ID1531]. Available on the Internet. URL: http://www.nice.org.uk. Accessed 2019 June 11.
4. Ruberg FL, Grogan M, Hanna M, et al. Transthyretin amyloid cardiomyopathy. J Amer Coll Cardiology. 2019;73(22):2872-91.
5. Vyndaqel and Vyndamax (tafamidis) [prescribing information]. New York, NY: Pfizer Labs; January 2026.


## Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- June 13, 2023: Expanded diagnosis requirements to allow confirmation of diagnosis by a technetium pyrophosphate scan, cardiac biopsy, other lab tests, respectively, or presence of genetic mutation. Removed “Documentation in the patient’s medical record of transthyretin (TTR) mutation.” from Reauthorization Criteria. Added documentation the requested medication will not be concomitantly with another medication indicated for the management cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (effective September 1, 2023).
- May 14, 2024: No changes
- April 8, 2025: Simplified diagnosis requirements in the Initial Authorization Criteria. Added “Documentation the absence of monoclonal protein in serum and urine, obtained through laboratory work, to rule out light chain amyloidosis

cardiomyopathy” and “Documentation of diagnostic cardiac imaging demonstrating cardiac involvement” to Initial Authorization Criteria and Reauthorization Criteria (eff 7/1/25).

- April 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.