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5.75.028

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	May 24, 2019
Subject:	Vyndaqel Vyndamax	**Page:**	1 of 4

Last Review Date: March 6, 2026

Vyndaqel Vyndamax

Description

Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)

Background

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process (1).

Regulatory Status

FDA-approved indication: Vyndaqel and Vyndamax are indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization (1).

Vyndaqel and Vyndamax are not substitutable on a per mg basis (1).

Vyndaqel and Vyndamax have not been studied in: New York Heart Association (NYHA) class IV, primary light chain amyloidosis, prior liver or heart transplantation, or implanted cardiac mechanical assist device (1).

The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).

Related policies

Amvuttra, Onpattro, Tegsedi

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vyndaqel and Vyndamax may be considered **medically necessary** if the conditions indicated below are met.

Vyndaqel and Vyndamax may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Hereditary or wild type transthyretin-mediated amyloidosis (ATTR) cardiomyopathy

AND ALL of the following:

1. Diagnosis has been confirmed by a genetic test **OR** tissue biopsy showing amyloid deposition
2. Clinical signs and symptoms of cardiac involvement by **ALL** of the following:
   a. End-diastolic interventricular septal wall thickness > 12 mm by echocardiography
   b. History of heart failure with at least one prior hospitalization for heart failure **OR** clinical evidence of heart failure with signs and symptoms of volume overload or elevated intracardiac pressures requiring treatment with a diuretic for improvement
   c. Baseline NT-proBNP ≥ 600 pg/mL

AND NONE of the following:

1. NYHA class IV heart failure
2. Light-chain amyloidosis
3. History of heart or liver transplantation
4. Implanted cardiac mechanical assist device, such as left ventricular assist device (LVAD)

a. Implanted devices for heart rhythm such as a pacemaker or cardiac defibrillator are allowed

5. Severe malnutrition

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) cardiomyopathy

AND the following:

1. Patient's condition has improved or stabilized (e.g., reduced number of hospitalizations, improved 6-minute walk test (6-MWT), or improved Kansas City Cardiomyopathy Questionnaire Overall Summary Score (KCCQ-OS)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
Vyndaqel 20 mg capsules	360 capsules per 90 days
Vyndamax 61 mg capsules	90 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process. The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vyndaqel and Vyndamax while maintaining optimal therapeutic outcomes.

References

1. Vyndaqel and Vyndamax [package insert]. New York, NY: Pfizer Inc.; October 2023.

Policy History

Date	Action
May 2019	Addition to PA
June 2019	Annual review
September 2019	Annual review. Addition of requirement for prescriber to monitor for NSAID, CCB, or digoxin toxicity and no heart failure not due to ATTR, light-chain amyloidosis, transplant, severe malnutrition per SME
December 2019	Revised requirement to patient must have wild type ATTR or genetic confirmation of hereditary ATTR
March 2020	Annual review and reference update
August 2020	Revised requirement that patients cannot have an implanted cardiac mechanical assist device, such as left ventricular assist device (LVAD) but implanted devices for heart rhythm are allowed
September 2020	Annual review
December 2021	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.75.028
December 2023	Annual review and reference update
March 2024	Annual editorial review and reference update. Revised requirements per Association
March 2025	Annual review
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.