

**Vyndaqel® (tafamidis meglumine)  
Vyndamax® (tafamidis)  
Effective 04/01/2020**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

Vyndaqel and Vyndamax are transthyretin stabilizers 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.

**Coverage Guidelines**

Authorization may be granted for members who are currently receiving treatment with Vyndaqel or Vyndamax excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member is ≥ 18 years of age
2. The diagnosis of cardiomyopathy of Wild type or Hereditary Transthyretin-mediated Amyloidosis confirmed by ANY of the following
  - a. Results from genetic testing showing mutations in the TTR gene
  - b. Presence of amyloid deposits in biopsy tissue with confirmed TTR
  - c. TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry
3. The medication is being prescribed by a cardiologist or in consultation with a cardiologist.

**Continuation of Therapy**

Reauthorization requires physician documentation of improvement of member’s condition.



**Limitations**

- 1. Approvals will be authorized for 12 months
- 2. The following quantity limits apply:

Vyndaqel 80mg	120 capsules per 30 days
Vyndamax 61mg	30 capsules per 30 days

**References**

- 1. Vyndaqel and Vyndamax [package insert]. New York, NY: Pfizer Labs.; May 2019.
- 2. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018 Sep 13; 379(11):1007-1016.

**Review History**

- 11/20/2019 – Reviewed P&T
- 11/25/2019 – Reviewed and approved DCC
- 01/22/2020 – Approved P&T Mtg
- 11/16/2022 –Separated out MH vs Comm/Exch. No clinical changes.

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