

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

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<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  $\geq$  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
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Vyndamax 61mg	30 capsules per 30 days
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### 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 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

