

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

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	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 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

