

**Vyndaqel (tafamidis meglumine)  
 Vyndamax (tafamidis)  
 Effective 07/01/2025**

<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 Benefit</b>	Phone: 833-895-2611	Fax: 888-656-6671
	<b>Pharmacy Benefit</b>	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Vyndaqel (tafamidis) capsules and Vyndamax (tafamidis) capsules 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 new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program

#### OR

Authorization may be granted when all of the following criteria are met:

1. Member is 18 years of age or older
2. Diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis
3. Diagnosis is confirmed by at least ONE of the following
  - a. Presence of a transthyretin (TTR) mutation (e.g., V122I)
  - b. Presence of TTR amyloid deposits in biopsy tissue
  - c. Cardiac magnetic resonance imaging or scintigraphy scan suggestive of amyloidosis and light chain testing has ruled out light chain amyloidosis (AL amyloidosis)
4. Member has New York Heart Association (NYHA) Functional Class I, II, or III heart failure
5. Requested medication is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., diflunisal, Attruby)
6. Requested medication is prescribed by or in consultation with a cardiologist

### Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation is submitted demonstrating member has had a positive clinical response to therapy (e.g., improvement in 6-minute walk test [6MWT] compared to baseline, decreased number of cardiovascular-related hospitalizations, improvement in Kansas City Cardiomyopathy Questionnaire, improvement in signs and symptoms, slowing of disease progression)

## Limitations

1. Initial and reauthorization approvals will be authorized for 12 months
2. The following quantity limits apply:

Drug Name	Quantity Limit
Vyndaqel 80mg	120 capsules per 30 days
Vyndamax 61mg	30 capsules per 30 days

## References

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3. Barroso FA, Judge DP, Ebede B, et al. Long-term safety and efficacy of tafamidis for the treatment of hereditary transthyretin amyloid polyneuropathy: results up to 6 years. *Amyloid*. 2017;24(3):194-204.
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## 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.

04/09/2025 – Reviewed and Updated for April P&T. Updated policy to clarify diagnosis requirements and require that member has NYHA class I, II, or III heart failure. Added requirement that requested medication will not be



used in combination with a TTR silencer or stabilizer. Updated reauthorization criteria to include examples of a positive clinical response to therapy. Effective 07/01/2025.

