

Market Applicability									
Market	DC	GA	KY	MD	NJ	NY	TN	TX	WA
Applicable	X	X	X	X	X	X	NA	NA	X

# Tafamidis

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Vyndamax (tafamidis) Vyndaqel (tafamidis meglumine)	May be subject to quantity limit

## APPROVAL CRITERIA

Requests for tafamidis (Vyndaqel, Vyndamax) may be approved if the following criteria are met:

- I. Individual has a diagnosis of wild type or hereditary transthyretin amyloid cardiomyopathy confirmed by biopsy and DNA mutation analysis (Bozkurt, 2016; Maurer, 2018); **AND**
- II. Individual is using for the treatment of New York Heart Association class I, II or III heart failure symptoms (Maurer, 2018).

Tafamidis (Vyndaqel, Vyndamax) may not be approved for the following:

- I. Individual has a history of liver or heart transplantation.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

## Key References:

1. Bozkurt B, Colvin M, Cook J, et al. Current diagnostic and treatment strategies for specific dilated cardiomyopathies: a scientific statement from the American Heart Association. *Circulation*. 2016;134:e579–e646.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: May 9, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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5. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. *NEJM*. 2018; 379(11):1007-16.
6. McKenna WJ. Clinical manifestations and diagnosis of amyloid cardiomyopathy. Last updated: August 23, 2017. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: April 27, 2019.
7. McKenna WJ. Treatment of amyloid cardiomyopathy. Last updated: August 31, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: April 27, 2019.

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