Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	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

Initial 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).

Continuation requests for tafamidis (Vyndaqel, Vyndamax) may be approved if the following criterion is met:

I. There is documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to reduction in hospitalizations, improvement or stabilization in 6-Minute Walk Test, improvement in symptom burden or frequency).

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

I. Individual has a history of liver or heart transplantation; **OR**
II. Individual is using in combination with Onpattro or Tegsedi.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Key References:

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2. 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.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: December 2, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Gertz MA, Benson MD, Dyck PJ, et. al. Diagnosis, Prognosis, and Therapy of Transthyretin Amyloidosis. *J Am Coll Cardiol*. 2015;66(21):2451-2466.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. *NEJM*. 2018; 379(11):1007-16.
8. McKenna WJ. Clinical manifestations and diagnosis of amyloid cardiomyopathy. Last updated: August 23, 2017. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 12, 2019.
9. McKenna WJ. Treatment of amyloid cardiomyopathy. Last updated: May 10, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 12, 2019.

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.