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;

AND

II. Documentation is provided that diagnosis has been confirmed by (Dorbala 2021, Kittleson 2023)):
   A. Endomyocardial or extracardiac biopsy;
      OR
   B. Both of the following:
      1. Radionuclide scintigraphy (99mTc-PYP/DPD/HMDP) with grade 2 or 3 uptake; **AND**
      2. Absence of monoclonal protein on serum free light chain assay and serum and urine immunofixation;

AND

III. 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. Documentation is provided to show 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 Amvuttra, Attruby, Onpattro, Tegsedi, or Wainua.

Key References:

1. Ando Y, Coelho T, Berk JL, et. al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. *Orphanet J Rare Dis*. 2013;8(31).
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: July 3, 2024.
4. Dorbala S, Ando Y, Bokhari S, et. al. ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI Expert Consensus Recommendations for Multimodality Imaging in Cardiac Amyloidosis: Part 2 of 2-Diagnostic Criteria and Appropriate Utilization. *Circ Cardiovasc Imaging*. 2021;14:e30.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Fontana M. Cardiac amyloidosis: Treatment and prognosis. Last updated: April 24, 2024. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 4, 2024.
7. Fontana M. Cardiac amyloidosis: Epidemiology, clinical manifestations, and diagnosis. Last updated: May 2, 2024. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 4, 2024.
8. Gertz MA, Benson MD, Dyck PJ, et. al. Diagnosis, Prognosis, and Therapy of Transthyretin Amyloidosis. *J Am Coll Cardiol*. 2015;66(21):2451-2466.
9. Heidenreich P, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *J Am Coll Cardiol.* 2022 May;79(17):e263–e421.
10. Kittleson M, Ruberg F, et al. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. *JACC.* 2023; 81(11):1076–1126.
11. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
12. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. *NEJM*. 2018; 379(11):1007-16.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.