CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Vyndaqel and Vyndamax are transthyretin (TTR) 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. Stabilizing TTR slows the formation of amyloid. Efficacy was demonstrated in the ATTR-ACT clinical trial. Vyndaqel and Vyndamax were approved by the FDA in 2019 and are administered as oral capsules.
ATTR is a rare disease in which the transport protein transthyretin (TTR) is unstable and misfolds, accumulating as amyloid fibrils in the body. In the cardiomyopathy form of ATTR (ATTR-CM), the amyloid accumulates in the myocardium, resulting in heart failure. The hereditary form of ATTR (hATTR) is caused by a mutation in the TTR gene, whereas wild type ATTR (ATTRwt) is associated with aging.

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) will be considered for coverage when the following criteria are met:

Transthyretin Amyloid Cardiomyopathy (ATTR-CM)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis; AND
3. Member has a documented diagnosis of ATTR-CM confirmed by one of the following (a or b):
   a) Endomyocardial biopsy showing amyloidosis, with confirmatory TTR amyloid typing (by immunohistochemistry and/or mass spectrometry)
   b) Both of the following:
      i) Positive technetium-99m (99mTc) bone scintigraphy scan (Perugini grade 2 or 3 myocardial uptake), and
      ii) Absence of monoclonal light chains (based on both immunofixation electrophoresis (IFE) of serum and urine, and serum free light chain (sFLC) analysis; AND
4. Member has evidence of cardiac wall thickening with left ventricular (LV) wall thickness ≥ 12 mm (measured by ECHO or CMR); AND
5. Member has a history of heart failure (HF) with at least 1 prior hospitalization for HF or clinical evidence of HF (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures that required/requires treatment with a diuretic; AND
6. Member has New York Heart Association (NYHA) functional class I-III symptoms due to ATTR-CM; AND
7. Member has tried and failed Attruby; AND
8. Member does NOT have any of the following:
   a) Prior liver or heart transplantation or an implanted cardiac device

b) Use of Vyndagel or Vyndamax in combination with another TTR stabilizer or a TTR silencer.

9. **Dosage allowed/Quantity limit:**
   Vyndaqel: 80 mg orally once daily. (120 capsules per 30 days)
   Vyndamax: 61 mg orally once daily. (30 capsules per 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document a positive clinical response to therapy such as a reduction in the decline of functional capacity (e.g., distance walked on 6-minute walk (6MWT) improved), reduction in the decline in quality of life, or reduced cardiovascular-related hospitalizations.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/08/2019	New policy for Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) created.
07/21/2020	Expanded prescriber to include physicians who specialize in treating amyloidosis.
08/04/2022	Transferred to new template. Updated and added references. Added QL. Moved MRI and echo to a separate bullet. Removed 6MWT requirement. Added NYHA I-III. Changed “cardiac pyrophosphate imaging” to “nuclear scintigraphy imaging with technetium radiotracers.” Minor revision to the renewal criteria wording.
01/28/2025	Updated references. Updated diagnostic confirmation details regarding biopsy, amyloid typing, scintigraphy; added absence of light chains (Heidenreich 2022, Dorbala 2020, Brito 2023). Separated LV wall thickness, history of HF, and NYHA class from other diagnostics (for readability). Removed genetic test requirement for hATTR (drug can be used in either wild-type or variant disease). Simplified wording for LV wall thickness. Clarified that NYHA symptoms are due to ATTR-CM. Changed not to be used with “another hATTR drug” to not to be used with “another TTR stabilizer or a TTR silencer.”

References:

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5. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical

Practice Guidelines [published correction appears in J Am Coll Cardiol. 2023 Apr 18;81(15):1551. doi: 10.1016/j.jacc.2023.03.002]. *J Am Coll Cardiol*. 2022;79(17):e263-e421. doi:10.1016/j.jacc.2021.12.012
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8. Brito D, Albrecht FC, de Arenaza DP, et al. World Heart Federation Consensus on Transthyretin Amyloidosis Cardiomyopathy (ATTR-CM). *Glob Heart*. 2023;18(1):59. Published 2023 Oct 26. doi:10.5334/gh.1262
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