CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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 diagnosis of ATTR-CM confirmed by ALL of the following:
   a) Identification of amyloid deposits via biopsy or nuclear scintigraphy imaging with technetium radiotracers
   b) One of the following:
      i) For hATTR (hereditary): Genetic testing confirming TTR gene mutation
      ii) For ATTRwt (wild type): TTR precursor protein identification by immunohistochemistry, scintigraphy or mass spectrometry
   c) Evidence of cardiac wall thickening by cardiac MRI or by echocardiography with an end-diastolic interventricular septal wall thickness exceeding 12 mm
   d) Medical 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 for improvement
   e) New York Heart Association (NYHA) functional class I-III; AND
4. 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 hATTR drug (e.g., Amvuttra, Tegsedi, Onpattro).

5. **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.

References:

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