CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Vyndaqel(tafamidis meglumine) and Vyndamax(tafamidis) are **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CARDIOMYOPATHY OF WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTR-CM)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis (e.g., hematologist, geneticist, etc.); AND
3. Member has diagnosis of ATTR-CM confirmed by ALL of the following:
   a) The demonstration of amyloid deposits via tissue biopsy or via cardiac pyrophosphate imaging;
   b) Genetic testing confirming TTR gene mutation for hereditary ATTR-CM or immunohistochemical analysis, scintigraphy, or mass spectrometry confirming presence of transthyretin precursor proteins for wild type ATTR-CM;
   c) Documentation of MRI or ECG results confirming cardiac involvement or 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 (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) that required/requires treatment with a diuretic for improvement; AND
4. Documented baseline of 6-minute walk test; AND
5. Member does **not** have ANY of the following:
   a) A New York Heart Association (NYHA) classification of IV;
   b) Presence of primary (light chain) amyloidosis;
   c) Prior liver or heart transplantation or implanted cardiac mechanical assist device; AND
6. Member is not receiving Vyndagel and/or Vyndamax with Tegsedi or Onpattro.
7. **Dosage allowed**: Vyndaqel 80 mg orally once daily, or Vyndamax 61 mg orally once daily.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., distance walked on 6-minute walk improved, reduced the decline in functional capacity and quality of life, cardiovascular-related hospitalizations decreased); AND
3. Member is not receiving Vyndagel and/or Vyndamax with Tegsedi or Onpattro.

If member meets all the reauthorization requirements above, 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 the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Primary amyloidosis

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.
06/10/2021	Annual review, no changes

References:

1. Vyndaqel and Vydamax [package insert]. New York, NY: Pfizer Labs.; May 2019.
2. ClinicalTrials.gov Identifier: NCT01994889. Safety and Efficacy of Tafamidis in Patients With Transthyretin Cardiomyopathy (ATTR-ACT). Available at: https://www.clinicaltrials.gov/ct2/show/NCT01994889?term=NCT01994889&rank=1.
3. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018 Sep 13; 379(11):1007-1016.
4. Shintani Y, et al. Monitoring treatment response to tafamidis by serial native T1 and extracellular volume in transthyretin amyloid cardiomyopathy. ESC Heart Fail. 2019;6(1):232–236.
5. Maurer MS, et al. Tafamidis in Transthyretin Amyloid Cardiomyopathy.Effects on Transthyretin Stabilization and Clinical Outcomes. Heart Failure. 2015;8:519–526.
6. Bokhari S, et al. (99m)Tc-pyrophosphate scintigraphy for differentiating light-chain cardiac amyloidosis from the transthyretin-related familial and senile cardiac amyloidoses. Circ Cardiovasc Imaging. 2013;6(2):195–201.
7. Brown EE, et al. Genetic testing improves identification of transthyretin amyloid (ATTR) subtype in cardiac amyloidosis. Amyloid. 2017 Jun;24(2):92-95.

Effective date: 01/01/2022
Revised date: 06/10/2021