UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Vyndaqel and Vyndamax

Program	Prior Authorization
Medication	Vyndaqel® (tafamidis meglumine), Vyndamax™ (tafamidis)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	6/2019
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis) are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

2. Coverage Criteria:

A. <u>Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)</u>

1. <u>Initial Authorization</u>

a. **Vyndaqel/Vyndamax** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

-AND-

(2) **<u>One</u>** of the following:

(a) Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

-OR-

(b) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

-OR-

(c) **All** of the following:

i. Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

-AND-

ii. Radionuclide imaging (^{99m}Tc-DPD, ^{99m}Tc-PYP, or ^{99m}Tc-HMDP) showing grade 2 or 3 cardiac uptake*

-AND-

iii. Absence of monoclonal protein identified in serum, urine immunofixation (IFE), serum free light chain (sFLC) assay

-AND-

(3) Prescribed by, or in consultation, with a cardiologist

-AND-

(4) Presence of clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)

-AND-

(5) Documentation of **both** of the following:

(a) **One** of the following:

i. Patient has New York Heart Association (NYHA) Functional Class I or II heart failure

-OR-

ii. **Both** of the following:

a. Patient has New York Heart Association (NYHA) Functional Class III heart failure

-AND-

b. Patient's cardiopulmonary functional status allows patient to ambulate 100 meters or greater in six minutes or less

-AND-

(b) Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to 600 pg/mL

-AND-

(6) **One** of the following:

(a) Patient is not receiving Vyndaqel/Vyndamax in combination with **either** of the following:

i. Onpattro (patisiran)
ii. Tegsedi (inotersen)

-OR-

(b) Physician attests that he/she will coordinate care with other specialist(s) involved in the patient's amyloidosis treatment plan to determine optimal long term monotherapy¥ treatment regimen

Authorization of will be issued for 12 months.

2. Reauthorization

a. **Vyndaqel/Vyndamax** will be approved based on **all** of the following criteria:

(1) Documentation that the patient has experienced a positive clinical response to Vyndaqel/Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

-AND-

(2) Prescribed by or in consultation with a cardiologist

-AND-

(3) Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

-AND-

(4) Patient is not receiving Vyndaqel/Vyndamax in combination with **either** of the following:

(a) Onpattro (patisiran)
(b) Tegsedi (inotersen)

Authorization will be issued for 12 months.

*May require prior authorization and notification
¥ Referring to monotherapy with Vyndaqel/Vyndamax, Onpattro, or Tegsedi

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Vyndaqel and Vyndamax [package insert]. Pfizer, Inc: New York, NY; April 2020.
2. Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.
3. Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016; 133:2404-12.
4. Mckenna WJ. Treatment of amyloid cardiomyopathy. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on December 16, 2020.)
5. Mckenna WJ. Clinical manifestations and diagnosis of amyloid cardiomyopathy. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on December 16, 2020.)
6. Falk RH. Diagnosis and management of the cardiac amyloidoses. Circulation 2005; 112:2047.

Program	Prior Authorization- Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis)
Change Control	
Date	Change
6/2019	New program.
2/2020	Updated program to address potential combination amyloidosis treatment.

2/2021	Annual review with no change to coverage criteria. Updated references.