UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2169-6
Program	Prior Authorization/Medical Necessity
Medication	Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis)
P&T Approval Date	6/2019, 2/2020, 2/2021, 2/2022, 2/2023, 9/2023
Effective Date	12/1/2023

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]:

A. Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

1. **Initial Authorization**

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

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

-AND-

(2) **One** 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. (Subsequent requests for combination therapy will result in an adverse coverage determination)

Authorization of therapy 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 of therapy will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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

3. Additional Clinical Programs:

- 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; June 2021.
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.
7. Kittleson MM, Maurer MS, Ambardekar AV, Bullock-Palmer RP, Chang PP, Eisen HJ, Nair AP, Nativi-Nicolau J, Ruberg FL; American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology. Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement From the American Heart Association. Circulation. 2020 Jul 7;142(1):e7-e22. doi: 10.1161/CIR.0000000000000792. Epub 2020 Jun 1. Erratum in: Circulation. 2021 Jul 6;144(1):e10. Erratum in: Circulation. 2021 Jul 6;144(1):e11. PMID: 32476490.

Program	Prior Authorization/Medical Necessity - Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis)
Change Control	
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.
2/2022	Annual review with no change to clinical criteria. Updated references.
2/2023	Annual review with no change to coverage criteria.
9/2023	Added reference to support requirement that Vyndamax/Vyndaqel are not used in combination with another agent for cardiac amyloidosis.