UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2169-8
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, 9/2024, 1/2025
Effective Date	4/1/2025

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. Echocardiagram 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 light chain amyloidosis

-AND-

(3) Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure

-AND-

(4) Physician attests that the patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM

-AND-

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

(a) History of heart failure, with at least one prior hospitalization for heart failure

-OR-

(b) Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

-AND-

(6) Prescribed by or in consultation with a cardiologist

-AND-

(7) Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

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

-AND-

(3) Prescribed by or in consultation with a cardiologist

-AND-

(4) Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

Authorization 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

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; October 2023.
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 2, 2024.)
5. Mckenna WJ. Clinical manifestations and diagnosis of amyloid cardiomyopathy. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on December 2, 2024.)
6. Kittleson MM, Maurer MS, et al. 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.
   Kittleson MM, Ruberg FL, et al. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023 Mar 21;81(11):1076-1126.

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.
9/2024	Annual review. Renamed and added examples of RNA-targeted therapies for ATTR amyloidosis.Updated and added references.
1/2025	Annual review. Updated clinical criteria for diagnosis of ATTR cardiac amyloidosis. Removed criteria allowing for temporary combination therapy. Added examples of RNA-targeted therapy. Updated references.