UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1283-8
Program	Prior Authorization/Notification
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-mediated amyloidosis with cardiomyopathy (ATTR-CM)

1. **Initial Authorization**

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

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

-AND-

(2) 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 **both** 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) 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.

3. Additional Clinical Programs:

- Medical Necessity may be in place
- 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. 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.
3. Kittleson, M, Ruberg, F. 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. *JACC.* 2023 Mar, 81 (11) 1076–1126.

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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 reference.
2/2022	Annual review with no change to clinical criteria. Updated reference.
2/2023	Annual review with no change to coverage criteria. Added state mandate footnote.
8/2023	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	Updated criteria for monotherapy use. Added example of RNA-targeted therapy for ATTR amyloidosis. Updated references.