UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2026 P 1283-9 |
| 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, 1/2026 |
| Effective Date | 4/1/2026 |

**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, 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. |
| 1/2026 | Annual review. No changes to coverage criteria. |