

Vyndamax™ (tafamidis) Vyndaqel® (tafamidis meglumine) (Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Vyndaqel 20 mg capsule: 4 capsules per day
- Vyndamax 61 mg capsule: 1 capsule per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- Vyndaqel: 80 mg daily
- Vyndamax: 61 mg daily

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ^{1,2,4,5}

- Therapy must not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen, patisiran, etc.); **AND**
- Patient has New York Heart Association (NYHA) class I or II heart failure (*i.e., excludes patients with NYHA Class III and IV disease*)*; **AND**
- Patient does not have primary (light chain) amyloidosis; **AND**
- Patient has not had a prior liver transplant; **AND**
- Patient does not have an implanted cardiac mechanical-assist device (e.g., left-ventricular assist device, etc.); **AND**

Cardiomyopathy of Wild Type Transthyretin-Mediated Amyloidosis (ATTR-CM)* † Φ ¹⁻⁶

- Patient has evidence of cardiac involvement by echocardiography with an end-diastolic interventricular septal wall thickness > 12 mm; **AND**
- Patient has a definitive diagnosis of ATTR amyloidosis as documented by amyloid deposition on tissue biopsy and identification of a pathogenic *TTR* variant and/or TTR precursor using molecular genetic testing (i.e., immunohistochemistry, scintigraphy or mass spectrometry); **AND**
 - Patient has a medical history of heart failure which required at least 1 prior hospitalization; **OR**
 - Patient has clinical evidence of heart failure, without a prior history of hospitalization for disease, manifested by signs or symptoms of volume overload or elevated intracardiac pressure (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) which requires/required treatment with a diuretic; **AND**
- Patient has a baseline 6-minute walk-test (6MWT) distance exceeding 100 m

**Note: Requests for patients with hereditary transthyretin-mediated amyloidosis (ATTR-m) genotype and/or NYHA Class III disease will be reviewed on a case-by-case basis.*

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,2,4,5}

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug; **AND**
- Disease response with treatment as evidenced by one or more of the following:
 - Decreased frequency of cardiovascular-related hospitalizations compared to pre-treatment baseline
 - Improvement in the total distance walked during 6-minute walk test (6MWT) compared to pre-treatment baseline

V. Dosage/Administration ^{1,2}

Indication	Dose
ATTR cardiomyopathy	<p><u>Vyndaqel</u></p> <ul style="list-style-type: none"> • Recommended dosage is 80 mg (four 20-mg tafamidis meglumine capsules) orally once daily. <p><u>Vyndamax</u></p> <ul style="list-style-type: none"> • Recommended dosage is 61 mg (one 61-mg tafamidis capsule) orally once daily. <p><i>* Vyndamax and Vyndaqel are not substitutable on a per mg basis</i></p>

VI. Billing Code/Availability Information

HCPCS code:

- J8499 – Prescription drug, oral, non chemotherapeutic, nos

NDC:

- Vyndaqel 20 mg capsules: 00069-1975-xx
- Vyndamax 61 mg capsules: 00069-8730-xx

VII. References

1. Vyndaqel [package insert]. New York, NY; Pfizer, Inc., June 2021. Accessed August 2022.
2. Vyndamax [package insert]. New York, NY; Pfizer, Inc., June 2021. Accessed August 2022.
3. Sekijima Y, Yoshida K, Tokuda T, et al. Familial Transthyretin Amyloidosis. Gene Reviews. Adam MP, Ardinger HH, Pagon RA, et al., editors. Seattle (WA): University of Washington, Seattle; 1993-2018.
4. Maurer MS, Schwartz JH, Gundapaneni B, ATTR-ACT Study Investigators. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med. 2018 Sep 13;379(11):1007-1016. doi: 10.1056/NEJMoa1805689. Epub 2018 Aug 27.
5. Maurer MS, Elliott P, Merlini G, ATTR-ACT Study Investigators. Design and Rationale of the Phase 3 ATTR-ACT Clinical Trial (Tafamidis in Transthyretin Cardiomyopathy Clinical Trial). Circ Heart Fail. 2017 Jun;10(6). pii: e003815. doi: 10.1161/CIRCHEARTFAILURE.116.003815. Review.
6. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8:31.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E85.82	Wild-type transthyretin-related (ATTR) amyloidosis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC