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

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I. Length of Authorization

Coverage will be provided for 12 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

Coverage is provided in the following conditions:

- The patient has ONE of the following:
  - ALL of the following:
    - A diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis confirmed by testing [e.g., stannous pyrophosphate (PYP) scanning, monoclonal antibody studies, biopsy, scintigraphy, genetic testing (TTR genotyping)]; **AND**
    - The requested agent is FDA approved for use in cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis; **AND**
    - The patient has clinical manifestations of cardiomyopathy (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema); **OR**
  - The patient has another FDA approved indication for the requested agent and route of administration; **AND**
- If the patient has an FDA approved indication, then ONE of the following:

- The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
- The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication; **AND**

- The patient has NOT received a liver transplant; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient will NOT be using the requested agent in combination with another agent targeted in this program [i.e., Tegsedi (inotersen), Wainua (eplontersen)], Onpattro (patisiran), OR Amvuttra (vutrisiran) for the requested indication; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

IV. Renewal Criteria

Coverage may be renewed based upon the following criteria:

- The patient has been previously approved for the requested agent through the plan's Prior Authorization process; **AND**
- The patient has had clinical benefit with the requested agent; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient has NOT received a liver transplant; **AND**
- The patient will NOT be using the requested agent in combination with another agent targeted in this program [i.e., Tegsedi (inotersen), Wainua (eplontersen)], Onpattro (patisiran), OR Amvuttra (vutrisiran) for the requested indication; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

V. Dosage/Administration

Indication	Dose
Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM)	<u>Vyndaqel</u> • Recommended dosage is 80 mg (four 20-mg tafamidis meglumine capsules) orally once daily. <u>Vyndamax</u> • Recommended dosage is 61 mg (one 61-mg tafamidis capsule) orally once daily. ** Vyndamax and Vyndaqel are not substitutable on a per mg basis*

VI. Billing Code/Availability Information

<u>HCPCS code</u>:

- 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., April 2023. Accessed August 2023.
2. Vyndamax [package insert]. New York, NY; Pfizer, Inc., April 2023. Accessed August 2023.
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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