Clinical Policy: Tafamidis (Vyndaqel, Vyndamax)

Reference Number: IN.CP.PHAR.432
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Tafamidis meglumine (Vyndaqel®) and tafamidis (Vyndamax™) are transthyretin stabilizers.

FDA Approved Indication(s)

Vyndaqel and Vyndamax are indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Transthyretin Amyloid Cardiomyopathy (must meet all)**:**

1. Diagnosis of cardiomyopathy secondary to transthyretin-mediated amyloidosis (ATTR-CM), confirmed either histologically or by genetic testing (documentation required
2.)Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;
4. Dose does not exceed either of the following (a or b):
   a. Vyndaqel: 80 mg (4 capsules) per day;
   b. Vyndamax: 61 mg (1 capsule) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Transthyretin Amyloid Cardiomyopathy (must meet all)**:**

1. History of the requested agent within the past 90 days;
2. Dose does not exceed either of the following (a or b):
   a. Vyndaqel: 80 mg (4 capsules) per day;
   b. Vyndamax: 61 mg (1 capsule) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ATTR-CM: cardiomyopathy of transthyretin-mediated amyloidosis
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Tafamidis (Vyndaqel)	20 mg (4 capsules) PO QD	80 mg/day
Tafamidis (Vyndamax)	61 mg (1 capsule) PO QD	61 mg/day

VI. Product Availability

Drug Name	Availability
Tafamidis (Vyndaqel)	Capsules: 20 mg
Tafamidis (Vyndamax)	Capsules: 61 mg

VII. References

1. Vyndaqel, Vyndamax Prescribing Information. New York, NY; Pfizer, Inc.; May 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211996s000,212161s000lbl.pdf. Accessed April 6, 2021.
2. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379(11): 1007-1016.
3. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013; 8:31.
4. Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin

amyloidosis. Circulation. 2016;133(24):2404. Epub 2016 Apr 22.
5. Dorbala S, Ando Y, Bokhari S, et al. ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI expert consensus recommendations for multimodality imaging in cardiac amyloidosis: Part 1 of 2 - Evidence base and standardized methods of imaging. J Cardiac Failure; 2019: 24(11): e2-e39.
6. Dorbala S, Ando Y, Bokhari S, et al. ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI expert consensus recommendations for multimodality imaging in cardiac amyloidosis: Part 2 of 2-Diagnostic criteria and appropriate utilization. Journal of Cardiac Failure; 2019: 25(11): 854-865.
7. Witteles RM, Bokhari S, Damy T, et al. Screening for transthyretin amyloid cardiomyopathy in everyday practice. JACC, August 2019; 7(8): 709-16.
8. Kittleson MM, Maurer MS, Ambardekar AV, et al. Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement From the American Heart Association. Circulation; 2020 July: 142 (1): e7-e22.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created due to IN Medicaid Moratorium	12.2021	01.2022