RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Tafamidis (Vyndaqel, Vyndamax)**
Policy Number: **RxA.618**
Drug(s) Applied: **Tafamidis meglumine (Vyndaqel®) and tafamidis (Vyndamax™)**
Last Review Date: **03/2020**
Line of Business: **Commercial, TBD HIM*, Medicaid**

Background

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

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.

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

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

Clinical Policy

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 caused by ATTR;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;
4. Biopsy is positive for amyloid deposits; 5. One of the following (a or b):
   a. Confirmation of TTR precursor protein (e.g., by immunohistochemistry, scintigraphy, mass spectrometry);
   b. Confirmation of a TTR mutation by genetic testing;
6. Member has not had a liver transplant;
7. 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 .

II. Continued Therapy

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

1. Currently receiving medication via RxAdvance benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy, including but not limited to improvement or stabilization in any of the following parameters:
   a. Walking ability;
   b. Nutrition (e.g., body mass index);
   c. Cardiac related hospitalization;
   d. Cardiac procedures or laboratory tests (e.g., Holter monitoring, echocardiography, electrocardiogram, plasma BNP or NT-proBNP, serum troponin);
3. 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

III. Appendices

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

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 June 10, 2019.
2. Maurer MS, 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, Cruz MW, Ericzon BG, Ikeda S, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013; 8: 31.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	03/2020	03/06/2020