AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Vyndaqel (tafamidis meglumine) Vyndamax (tafamidis)	Page:	1 of 3
Effective Date:	2/13/2025	Last Review Date:	01/10/2025
Applies to:	☒ Illinois ☒ Pennsylvania Kids	☒ Maryland ☒ Virginia	☒ Florida Kids ☐ Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Vyndaqel and Vyndamax under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Vyndaqel and Vyndamax are transthyretin stabilizers 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.
All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Vyndaqel
Vyndamax

Policy/Guideline:

Documentation
Submission of the following information is necessary to initiate the prior authorization review:
Initial requests:

- Chart notes or medical record documentation confirming the member demonstrates clinical symptoms of cardiomyopathy and heart failure
- For members with hereditary ATTR-CM: results confirming a mutation of the transthyretin (TTR) gene
- For biopsy proven disease:
  - Tissue biopsy confirming the presence of the transthyretin amyloid deposition
  - Immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy results confirming transthyretin precursor proteins
- For technetium-labeled bone scintigraphy proven disease:
  - A serum kappa/lambda free light chain ratio, serum protein immunofixation or urine protein immunofixation test result showing the absence of monoclonal proteins
  - Scintigraphy tracing results confirming presence of amyloid deposits

Continuation requests:

- Chart notes or medical record documentation confirming the member demonstrates a beneficial response to treatment (e.g., improvement in rate of disease progression as demonstrated by distance walked on the 6-minute walk test, the Kansas City

Cardiomyopathy Questionnaire–Overall Summary (KCCQ-OS) score, cardiovascular-related hospitalizations, NYHA classification of heart failure, left ventricular stroke volume, NT-proBNP level

Criteria for Initial Approval:

Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis

Authorization of 12 months may be granted for treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) when ALL the following criteria are met:

- The member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema).
- The diagnosis is confirmed by ONE of the following:
  - The member meets BOTH of the following:
    - Presence of transthyretin amyloid deposits on analysis of biopsy from cardiac or noncardiac sites.
    - Presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy
  - The member meets BOTH of the following:
    - Positive technetium-labeled bone scintigraphy tracing.
    - Systemic light chain amyloidosis is ruled out by a test showing absence of monoclonal proteins (serum kappa/lambda free light chain ratio, serum protein immunofixation, or urine protein immunofixation).
- For members with hereditary ATTR-CM, presence of a mutation of the TTR gene was confirmed.
- The member is not a liver transplant recipient.
- The requested medication will not be used in combination with acoramidis (Attruby), inotersen (Tegsedi), patisiran (Onpattro), vutrisiran (Amvuttra), or eplontersen (Wainua).

Continuation of Therapy

Authorization of 12 months may be granted for the continued treatment of ATTR-CM when BOTH of the following criteria are met:

- The member must meet all requirements in the initial criteria section.
- The member must have demonstrated a beneficial response to treatment with tafamidis therapy (e.g., improvement in rate of disease progression as demonstrated by distance walked on the 6-minute walk test, the Kansas City Cardiomyopathy Questionnaire–Overall Summary [KCCQ-OS] score, cardiovascular-related hospitalizations, NYHA classification of heart failure, left ventricular stroke volume,

N-terminal B-type natriuretic peptide [NT-proBNP] level). Documentation from the medical record must be provided

Approval Duration and Quantity Restrictions:

Initial Approval: 12 months

Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Vyndaqel and Vyndamax [package insert]. New York, NY: Pfizer Labs; April 2023.
2. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018 Sep 13; 379(11):1007-1016.
3. Maurer MS, Sabahat B, Thibaud D, et al. Expert consensus recommendations for the suspicion and diagnosis of transthyretin cardiac amyloidosis. Circ Heart Fail. 2019 Sep 4;12:9
4. Ruberg FL, Grogan M, et al. Transthyretin amyloid cardiomyopathy. J Am Coll Cardiol. 2019;73:2872-91.
5. Yadav JD, Othee H, Chan KA, Man DC, Belliveau PP, Towle J. Transthyretin Amyloid Cardiomyopathy-Current and Future Therapies. Ann Pharmacother. 2021;55(12):1502-1514