Effective date: 4/1/2020
Reviewed: 1/2020, 1/2021, 01/2022, 3/2023, 3/2024, 1/2025, 5/2025 Scope: Medicaid

VYNDAQEL (tafamidis meglumine)
VYNDAMAX (tafamidis)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Vyndaqel and Vyndamax are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild-type or variant/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.

II. CRITERIA FOR INITIAL APPROVAL

Cardiomyopathy of Wild Type or Hereditary Transthyretin-mediated Amyloidosis
Authorization of 6 months may be granted for treatment of cardiomyopathy of wild type or variant/hereditary transthyretin-mediated amyloidosis (ATTR-CM) when all of the following criteria are met:

A. Vyndaqel or Vyndamax is prescribed by, or in consultation with, a cardiologist.
B. Documentation that the member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) classified as New York Heart Association (NYHA) class I, II, or III disease.
C. Documentation that cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 mm).
D. The diagnosis is confirmed by one of the following:
    1. The member has documentation that meets both of the following:
        i. Presence of transthyretin amyloid deposits on analysis of biopsy from cardiac or noncardiac sites.
        ii. Presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy.
    2. The member has documentation that meets both of the following:
        i. Positive technetium-labeled bone scintigraphy tracing.
        ii. 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).
E. For members with variant/hereditary ATTR-CM, documentation of the presence of a mutation of the TTR gene was confirmed.
F. The member is not a liver transplant recipient.
G. The requested medication will not be used in combination with acoramidis (Attruby), patisiran (Onpattro), eplontersen (Wainua), or vutrisiran (Amvuttra).
H. If the request is for Vyndaqel/Vyndamax to be used in combination with a TTR-silencer/reducer (e.g., patisiran (Onpattro), eplontersen (Wainua)) to treat overlapping ATTR-CM and ATTR-PN, the member has a documented inadequate response, intolerance, or contraindication to monotherapy vutisiran (Amvuttra)

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for the continued treatment of ATTR-CM when all of the following criteria are met:

A. Documentation that the member must meet all initial authorization criteria.
B. Documentation (e.g., medical records, chart notes) that 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, left ventricular stroke volume, N-terminal B-type natriuretic peptide (NT-proBNP) level].
C. Documentation that the member has not progressed to NYHA class IV disease.

V. QUANTITY LIMIT

Vyndaqel 20mg has a quantity limit of 4 capsules per day.
Vyndamax 61mg has a quantity limit of 1 capsule per day.

VI. REFERENCES

1. Vyndaqel and Vydamax [package insert]. New York, NY: Pfizer Labs.; November 2024.
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. Mauer MS, Sabahat B, Thibaud D, et al. Expert Consensus Recommendations for the Suspicion and Diagnosis of Transthyretin Cardiac Amyloidosis. Circulation: Heart Failure. 2019 Sep 4;12:9.
4. Ruberg FL, Grogan M, et al. Transthyretin Amyloid Cardiomyopathy. J Am Coll Cardiol. 2019;73:2872-91.