BlueCross BlueShield
Federal Employee Program

VYNDAQEL (tafamidis meglumine), VYNDAMAX (tafamidis)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Hereditary or wild type transthyretin-mediated amyloidosis (ATTR) cardiomyopathy

AND ALL of the following:

1. Diagnosis has been confirmed by a genetic test **OR** tissue biopsy showing amyloid deposition
2. Clinical signs and symptoms of cardiac involvement by **ALL** of the following:
    a. End-diastolic interventricular septal wall thickness > 12 mm by echocardiography
    b. History of heart failure with at least one prior hospitalization for heart failure **OR** clinical evidence of heart failure with signs and symptoms of volume overload or elevated intracardiac pressures requiring treatment with a diuretic for improvement
    c. Baseline NT-proBNP ≥ 600 pg/mL

AND NONE of the following:

1. NYHA class IV heart failure
2. Light-chain amyloidosis
3. History of heart or liver transplantation
4. Implanted cardiac mechanical assist device, such as left ventricular assist device (LVAD)
    a. Implanted devices for heart rhythm such as a pacemaker or cardiac defibrillator are allowed
5. Severe malnutrition

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Prior - Approval Limits

Quantity

Strength	Quantity
Vyndaqel 20 mg capsules	360 capsules per 90 days
Vyndamax 61 mg capsules	90 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) cardiomyopathy

AND the following:

1. Patient's condition has improved or stabilized (e.g., reduced number of hospitalizations, improved 6-minute walk test (6-MWT), or improved Kansas City Cardiomyopathy Questionnaire Overall Summary Score (KCCQ-OS)

Prior - Approval *Renewal* Limits

Same as above