

### 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  $\geq$  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



### VYNDAQEL (tafamidis meglumine), VYNDAMAX (tafamidis)

## **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:

 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