I. Medication Description

Tafamidis is a selective transthyretin (TTR) stabilizer. Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, the rate-limiting step in the amyloidogenic process.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Vyndaqel or Vyndamax is provided for the treatment of wild type or hereditary transthyretin amyloid cardiomyopathy (ATTR-CM) in accordance with the following criteria:

- Member is 18 years of age or older AND
- Medication is prescribed by or in consultation with a pertinent specialist (e.g. cardiologist) with experience treating ATTR-CM AND
- Member has a diagnosis of ATTR-CM that has been confirmed by ONE of the following:
  - Presence of amyloid deposits identified on cardiac biopsy OR
  - A technetium pyrophosphate scan (i.e. nuclear scintigraphy) AND
- Genetic testing has been performed to identify a TTR mutation or wild type amyloidosis AND
- Cardiac involvement has been demonstrated by diagnostic cardiac imaging (e.g. echocardiography, cardiac magnetic resonance imaging) AND
- Member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g. dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, angina) AND
- Member does NOT have a diagnosis of New York Heart Association (NYHA) class IV heart failure AND
- Results from a baseline 6-minute walk test are submitted AND
- History of cardiovascular-related hospitalizations is provided

IV. Quantity Limitations

Coverage is available for the following:

- Vyndaqel: 120 capsules per 30 days.
- Vyndamax: 30 capsule per 30 days
V. Coverage Duration

Coverage is available for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed when the following criteria are met:

- First renewal (up to 12 months):
  - Demonstration of a positive clinical response to treatment (stabilization of disease or improvement in the rate of disease progression) as shown by any of the following compared to baseline:
    - 6-minute walk test
    - NYHA classification of heart failure
    - Number of cardiovascular-related hospitalizations AND
  - Absence of unacceptable toxicity from the drug

- Second and subsequent renewals (up to 12 months):
  - Demonstration of continued positive clinical response to treatment AND
  - Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as:
- Vyndaqel 20mg capsules
- Vyndamax 61mg capsules

VIII. Summary of Policy Changes

- 7/15/19: new policy

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.
The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.