Vyndaqel and Vyndamax (tafamidis)

Coverage Criteria:

1. Patient is ≥ 18 years of age; and,
2. Prescribed by a cardiologist or physician specializing in amyloidosis; and,
3. Patient is diagnosed with wild type or hereditary transthyretin-mediated amyloidosis cardiomyopathy (ATTR-CM); and,
4. Patient is diagnosed with NYHA class I, II or III at baseline (in the previous 6 months); and,
5. Patient has clinical history of heart failure (HF), with documentation of at least one of the following:
    a. At least one prior hospitalization for HF; or,
    b. Clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema); and,
6. Patient is negative for light chain amyloidosis; and,
7. No prior liver or heart transplant, or implanted cardiac mechanical assist device; and,
8. Cardiac involvement by echocardiography, with an end diastolic interventricular septal wall thickness > 12 mm; and,
9. Not prescribed concurrently with other hATTR medications (i.e. Onpattro, Tegsedi, Amvuttra); and,
10. Prescribed within the FDA approved dosing regimen.

Coverage Duration:

Initial authorizations and reauthorizations will be provided for 6 months

Renewal Criteria:

1. Patient has been seen by their prescriber in the past 12 months; and,
2. Prescribed by a specialist; and,
3. Patient has been adherent to therapy; and,
4. Medication has demonstrated efficacy by maintaining NYHA class I-III; and,
5. Prescribed within the FDA approved regimen.