Pharmacy Drug Policy Checklist

POLICY NAME	Vyndaqel/Vyndamax (tafamidis meglumine)	POLICY #	

Criteria

Exclusion Criteria – Any of the following prevents coverage

☐ **2.1** Concomitant use with any other disedase modifying therapy for ATIR-CM

Coverage Criteria

☐ **1.1** Diagnosis of transthyretin (ATIR) - mediated amyloidosis with cardiomyopathy (ATIR-CM)

☐ **1.2** One of the following:

- Documentation that the patient has a pathogenic TIR mutation (e.g., V30M), or
- Cardiac or non-cardiac tissue biopsy demonstrating histologic confirmation of ATIR amyloid deposits, or
- ALL of the following:
- Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, and
- Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake, and
- Absence of monoclonal protein identified in serum, urine immunofixation (JFE), serum free light chain (sFLC) assay

☐ **1.3** Prescribed by or in consultation with a cardiologist (heart doctor)

☐ **1.4** Presence of clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)

☐ **1.5** Documentation of BOTH of the following:

- One of the following:
- Patient has New York Heart Association (NYHA) Functional Class I or II heart failure, or
- Patient has New York Heart Association (NYHA) Functional Class III heart failure, and patient's cardiopulmonary functional status allows patient to ambulate I 00 meters or greater in 6 minutes or less
- Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to

pg/mL

☐ **1.6** Documentation of previous trial and failure or contraindication to Attruby (acoramidis)