curative

ATTR Amyloid Cardiomyopathy Prior Authorization Drug List A

Drug(s) Applied:	**Vyndaqel** (tafamidis meglumine)**, Vyndamax** (tafamidis), **Attruby** (acoramidis)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. ATTR amyloid cardiomyopathy also known as ATTR cardiac amyloidosis** as indicated by chart notes within past 90 days
  1. If for Vyndaqel or Vyndamax, must have documented failure to Attruby **and**
  2. Diagnosis of wild-type transthyretin amyloid cardiomyopathy (ATTRwt-CM) or variant transthyretin amyloid cardiomyopathy (ATTRv-CM) confirmed by testing of either monoclonal antibody studies with scintigraphy with radiopharmaceutical technetium, tissue biopsy, or genetic testing (TTR gene sequencing) **and**
  3. Patient has clinical manifestations of cardiomyopathy (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) **and**
  4. Patient has NYHA functional class I, II, or III **and**
  5. Patient has not received a liver transplant **and**
  6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) **and**
  7. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another TTR-directed therapy (e.g. Amvuttra, Attruby, Onpattro, Vyndaqel, Vyndamax, or Wainua)

Approval Duration: 12 months for Attruby; 3 months for Vyndaqel or Vyndamax

II. Continued Therapy Criteria
- **A. Amyloid cardiomyopathy** as indicated by chart notes within past 12 months
  1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
  2. Documented clinical benefit since starting the requested agent (i.e., improvement or stabilization in 6-minute walking distance (6MWD) or other heart failure-related sign/symptom, reduction in cardiovascular-related

hospitalizations) **and**

3. Patient has not received a liver transplant **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., cardiologist, geneticist, neurologist) **and**
5. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another TTR-directed therapy (e.g. Amvuttra, Attruby, Onpattro, Vyndaqel, Vyndamax, or Wainua)

Approval Duration: 12 months for Attruby; 3 months for Vyndaqel or Vyndamax

Policy Owned by: Curative PBM team