

Clinical Oversight Review Board (CORB) Criteria for Prescribing/  
Criteria-Based Consultation (CBC) Criteria for Coverage

# Tafamidis (Vyndamax) Tafamidis Meglumine (Vyndaqel)

**Notes:**

- \* Concurrent treatment has not been studied and is considered experimental

Non-Formulary **tafamidis (Vyndamax)** and **tafamidis meglumine (Vyndaqel)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

**Initiation (new start) criteria:** Non-formulary **tafamidis (Vyndamax)** and **tafamidis meglumine (Vyndaqel)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by a cardiologist
- Patient is at least 18 years of age
- Diagnosis of Cardiac Amyloidosis
- Evidence of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) demonstrated by either:
  - Positive biopsy demonstrating transthyretin (TTR)-amyloid deposition
  - Meeting all three of the following:
    - Diagnosis of heart failure (defined as stage C heart failure (HF) plus NYHA class I, II, or III)
    - Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either:
      - Grade 2 or 3 using the Perugini Grade 1-3 scoring system
      - Calculated heart-to-contralateral (H/CL) ratio of 1.5 or greater
    - Absence of monoclonal gammopathy after testing for serum immunofixation (IFE) and serum free light chains
- Medical history of HF with at least 1 prior hospitalization for HF or clinical evidence of HF (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures that require treatment with diuretic
- Patient does NOT have glomerular (GFR) or creatinine clearance (CrCl) less than 25 ml/min
- Patient is NOT receiving inotersen or patisiran\*
- Patient has NOT had prior heart or liver transplantation
- Patient does NOT have an implanted cardiac mechanical assist device

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Revised: 12/09/21  
Effective: 02/03/22

All plans offered and underwritten by  
Kaiser Foundation Health Plan of the Northwest