

Tafamidis (VYNDAMAX)

Transthyretin Amyloid Cardiomyopathy (ATTR-CM)

Criteria for Use

October 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should **NOT** receive tafamidis

- Heart failure without definitive evidence of transthyretin-mediated amyloidosis (ATTR) (e.g., heart failure secondary to ischemic heart disease)
- Patient receiving concomitant therapy for ATTR amyloidosis (e.g., patisiran, eplontersen, inotersen, vutrisiran, acoramidis)¹
- End stage heart disease and anticipated survival < 1 year

Inclusion Criteria

All the following must be fulfilled to receive tafamidis.

- Provider is a VA or VA Community Care cardiologist or locally designated ATTR-CM provider
- Diagnosis of wild type or hereditary TTR genotype ATTR-CM based on 1) endomyocardial biopsy OR 2) echo/MRI suggestive of amyloidosis confirmed with radionuclide imaging (e.g., technetium-pyrophosphate [Tc99-PYP] scintigraphy)
- Assessment of monoclonal protein screen for and exclusion of light chain (AL) amyloidosis²
- History of symptomatic heart failure³
- Discussion with patient/caregiver/family member regarding realistic treatment expectations and discontinuation should be documented

Additional Inclusion Criteria

- For females who can become pregnant: Counseling provided on potential risks vs. benefits of treatment
1. Combination disease modifying ATTR-CM therapy has not been specifically studied or determined to be superior to single agent therapy.
 2. In rare cases, ATTR-CM and AL amyloidosis may coexist; these cases should be adjudicated locally.
 3. At least one hospitalization for heart failure OR clinical evidence of heart failure manifested by signs and symptoms of volume overload or elevated intracardiac pressures

Prepared: September 2019. Updated Sept 2022, Mar 2023, Jan 2024, Feb 2025, Jun 2025, Oct 2025. Contact: Lisa Longo, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Service (12PBM)
