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[The information contained in this template letter is provided by Pfizer for informational purposes for patients who have been prescribed VYNDAMAX® (tafamidis) or you can modify for patients who have been prescribed tafamidis meglumine. There is no requirement that any patient or healthcare provider use any Pfizer product in exchange for this information, and this template letter is not meant to substitute for a prescriber's independent medical decision-making. Additional resources, including checklists for Prior Authorizations and Appeals, are available at http://www.vyndalink.com/hcp/access]

<<Date>>

Insurer Details:
<<Insurance Company Name>>
<<Medical Director>>
<<Insurer Address>>
<<State, City, Zip Code>>

Patient Details:
<<Patient First and Last Name>>
<<Group Number>>
<<Policy Number>>

To Whom It May Concern,

I am writing on behalf of my patient, *<<Patient First and Last Name>>*, to request that you approve coverage for VYNDAMAX® (tafamidis) as a medically necessary treatment. VYNDAMAX is indicated for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization.

This letter provides information about my patient's medical history, diagnosis, and details regarding the medical necessity of the VYNDAMAX treatment being requested.

Overview of ATTR-CM
Transthyretin amyloid cardiomyopathy is a rare and fatal condition characterized by restrictive cardiomyopathy and progressive heart failure. ATTR-CM is caused by deposition of transthyretin amyloid fibrils in the heart. In patients with ATTR-CM, transthyretin breaks down and forms what are called amyloid fibrils. These fibrils build up in heart tissue, causing damage to cells and limiting the heart's ability to pump blood. As more amyloid is deposited, the heart progressively stiffens and fails.

Patients with ATTR-CM typically experience symptoms of heart failure. As the symptoms worsen over time, most patients have difficulty performing even the most basic activities of daily living.[1] Patients usually die within three to five years of receiving a diagnosis.[2]

References: 1. Amyloidosis Foundation. Understanding the patient voice in hereditary transthyretin-mediated amyloidosis (ATTR amyloidosis). http://amyloidosissupport.org/support_groups/fam_isabell_attr.pdf. Accessed March 6, 2020. **2.** National Center for Biotechnology Information (NCBI). Transthyretin (TTR) Cardiac Amyloidosis. https://www.ncbi.nlm.nih.gov/pmc/article/PMC3501197. Accessed March 6, 2020.

ATTR-CM can be an inherited condition (“hereditary” form), or it can occur sporadically in elderly patients without a known genetic predisposition (“wild-type” form). The two forms of the disease may have a similar clinical presentation, though the disease may progress more quickly in those with the hereditary form.

Summary of Patient’s Medical History

[Note: Exercise your medical judgement and discretion when providing a diagnosis and characterization of the patient’s medical condition.]

<<You may want to include:>>

- Date and method of ATTR-CM diagnosis, including ICD-10-CM code(s)
  - Date of ATTR-CM diagnosis
  - Diagnostic evaluation(s): *[Describe diagnostic evaluative steps to determine that the patient has ATTR-CM with light-chain amyloidosis excluded.]*
  - If applicable, genetic testing results
- Patient’s history and current condition
  - Symptoms associated with ATTR-CM: *[Describe the clinical evidence of heart failure.]*
  - Signs of ATTR-CM observed via imaging and/or cardiac biomarker tests
  - Patient’s functional status
  - Relevant comorbidities
  - Cardiac device, such as pacemaker or ICD *[You may want to characterize the patient’s specific cardiac device and attach the study protocol for the phase 3 ATTR-ACT trial of tafamidis, including inclusion and exclusion criteria for clinical trial participants.]*
  - Intracardiac mechanical assist device(s)
- Previous and/or current treatments
- Summary of professional opinion of the patient’s likely prognosis or disease progression without treatment with VYNDAMAX

Rationale for Treatment

[Modify as appropriate based upon your independent medical judgement.]

Given the patient’s history and current clinical status, the patient is appropriate for the approved indication for VYNDAMAX, and I believe treatment of *<<Patient First and Last Name>>* with VYNDAMAX is medically necessary. The accompanying package insert provides the approved clinical information for VYNDAMAX.

If you have further questions, please contact my office at *<<MD Primary Phone>>*.

Sincerely,

<<Physician Name>>

<<Provider Number>>