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VYNDAMAX PAYER COVERAGE DOCUMENTS

Once you have prescribed VYNDAMAX for your patient, a prior authorization (PA) may be needed. Please review the reference materials contained within this document. They can be a resource for you in helping patients gain access to VYNDAMAX.

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For Healthcare Providers

NAVIGATING THE POST-PRESCRIPTION PATHWAY

There are 3 ways for patients to receive their medication once you have prescribed VYNDAMAX®:

National Specialty Pharmacy

Send your prescription to one of the national Specialty Pharmacies in the defined distribution network.*

See the list at **www.VyndamaxHCP.com**.

IDN Specialty Pharmacy (where applicable)

Send your prescription to an eligible IDN Specialty Pharmacy.

VyndaLink®

Send your prescription to VyndaLink, a program designed to help provide medication access and patient support.†

No matter which pathway you choose, a prior authorization (PA) may be needed.‡

A PA checklist is included in this reference document.
You can also submit a PA request at no cost through CoverMyMeds®.
To learn more, visit covermymeds.com.§

IDN=integrated delivery network.

*Access to VYNDAQEL® (tafamidis meglumine) is available through the same defined distribution network.

† The same VyndaLink support offerings available to patients prescribed VYNDAMAX are also available to patients prescribed VYNDAQEL®.

‡ Please note that where a PA is required, the physician must submit required information directly to the patient's insurer.

§ This program is run by CoverMyMeds®, independently of Pfizer.

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PRIOR AUTHORIZATION CHECKLIST

Insurers are likely to require a prior authorization (PA) before approving coverage for VYNDAMAX® (tafamidis).* It is the responsibility of the physician to prepare and submit a PA. VyndaLink, your Pfizer Field Access Specialist, or Pfizer sales representative **cannot assist you** with completion or submission of PAs. Coverage criteria may vary, so it is important to review the individual guidelines for each insurer and medication. A network Specialty Pharmacy or the VyndaLink® support program can assist patients with benefits verification and help determine when a PA is required and what the criteria for coverage.

Options for additional support regarding the PA process

Contact your Pfizer Field Access Specialist (FAS). Your Pfizer sales representative can connect you with a Pfizer FAS for general questions regarding the PA process.

Visit www.CoverMyMeds.com for a resource that supports healthcare providers during the PA process at no cost.

Contact VyndaLink at 1-888-222-8475.

If your patient is enrolled in VyndaLink, please fax the PA outcome to VyndaLink at 1-888-878-8474.

When submitting a PA, the following information may be required before coverage is approved:

Patient Information

- ✓ Patient name
- ✓ Patient address
- ✓ Date of birth
- ✓ Social security number

Insurer Information

- ✓ Phone number
- ✓ Name of policyholder
- ✓ Plan ID number
- ✓ Group number
- ✓ Plan address
- ✓ Copy of front and back of the insurance card
- ✓ Completed and signed plan-specific PA form

Physician Information

- ✓ Physician name
- ✓ Physician specialty
- ✓ Tax ID number
- ✓ Physician office address
- ✓ Phone/fax number
- ✓ NPI number

Clinical Documentation, including

- ✓ Diagnosis (including ICD-10-CM code[s] for ATTR-CM)
- ✓ Diagnosis date and method
  - Biopsy and tissue location (e.g., cardiac, fat, salivary gland) **OR**
  - PYP cardiac imaging results, including visual score. In conjunction with PYP cardiac imaging, a report of the following tests to rule out AL amyloidosis may be required by payers
    - Serum/urine electrophoresis with immunofixation
    - Serumz free light-chain assay
  - If applicable, genetic testing and variant/wild-type determination

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- ✓ VYNDAMAX or tafamidis meglumine dose and start date of therapy, if currently on therapy
- ✓ Prior and/or current therapies being used to treat ATTR-CM
- ✓ Patient's history and current condition
  - Symptoms associated with ATTR-CM
    - Clinical evidence of heart failure (e.g., shortness of breath, fatigue, orthostatic hypotension, syncope)
  - Clinical signs of ATTR-CM observed via cardiac imaging or cardiac biomarkers
    - Echocardiogram (eg, concentric left ventricular hypertrophy, valve thickening, left atrial dilatation, bright or speckled myocardium)
    - Electrocardiogram (eg, discordance between QRS voltage and LV wall thickness, pseudoinfarct pattern, and electrical abnormalities including but not limited to atrial fibrillation and bundle branch block)
    - Cardiac MRI (eg, marked ECV expansion, elevated T1 signal, presence of and pattern of late gadolinium enhancement)
    - Cardiac biomarker levels (eg, NT-ProBNP, troponin T)
  - Patient's functional status
    - NYHA classification
    - 6-minute walk test distance
  - Relevant comorbidities
  - Pacemaker or implantable cardioverter defibrillator(s) (ICDs)
    Implanted cardiac mechanical assist device
    - Payers may require the ATTR-ACT study protocol, including inclusion and exclusion criteria for clinical trial participants
- ✓ Summary of your professional opinion as to the patient's likely prognosis or disease progression without treatment.

Please check your documentation to avoid potential denials. As a provider, you are responsible to submit information directly to insurers. Potential reasons for denial may include:

- Incorrect ICD-10-CM code(s) for ATTR-CM
- Lack of documentation supporting correct diagnosis and/or appropriate exclusion of light-chain amyloidosis

To make the strongest case for your patient, consider including:

- A Letter of Medical Necessity (see example at https://www.vyndalink.com/sites/default/themes/custom/vyndalink/pdfs/Sample-Letter-of-Medical-Necessity.docx)
- A copy of your chart notes with details about the patient's diagnosis, current condition, and treatment history

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APPEALS CHECKLIST

If a prior authorization (PA) is denied, the information below can support an appeal letter on behalf of your patient. Typically, a plan-specific form is required along with an appeal letter and supporting documentation. The insurer will outline any specific forms and timelines in their PA denial letter.

Options for additional support regarding the PA process

Contact your Pfizer Field Access Specialist (FAS). Your Pfizer sales representative can connect you with a Pfizer FAS for general questions regarding the PA process.

Contact VyndaLink at 1-888-222-8475

Insurer Information:

- ✓ Completed and signed plan-specific appeal form (may require patient signature as well in some cases)
- ✓ "Peer-to-peer" discussion with a medical reviewer at the health plan

Clinical Documentation, including:

- ✓ A Letter of Medical Necessity (see example at https://www.vyndalink.com/sites/default/themes/custom/vyndalink/pdfs/Sample-Letter-of-Medical-Necessity.docx)
- ✓ Chart notes with medical and treatment history, including:
  - Date and method of diagnosis
  - Severity of disease and current functional status
  - Response to all prior/current therapies
  - Any relevant comorbidities
  - Any relevant contraindications, if applicable (some insurers may request failure on alternative therapies)
- ✓ VYNDAMAX® (tafamidis) and tafamidis meglumine full Prescribing Information, available at www.VyndamaxHCP.com
- ✓ ATTR-ACT study protocol for inclusion and exclusion criteria (https://clinicaltrials.gov/ProvidedDocs/89/NCT01994889/Prot_000.pdf), and appropriate characterization of patient's cardiac device if applicable to the coverage denial
- ✓ Any clinical studies or relevant literature supporting the approval of VYNDAMAX and tafamidis meglumine
- ✓ Summary of your professional opinion of why the patient's recent symptoms, severity of condition and/or impact of disease warrant treatment with VYNDAMAX or tafamidis meglumine

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*The Appeals process is similar for VYNDAMAX and VYNDAQEL® (tafamidis meglumine).

SAMPLE LETTER OF MEDICAL NECESSITY

(Optional to accompany prio\r authorizations and/or denial appeals)

Options for additional support regarding the PA process

Contact your Pfizer Field Access Specialist (FAS). Your Pfizer sales representative can connect you with a Pfizer FAS for general questions regarding the PA process.

Contact VyndaLink at 1-888-222-8475

The information contained in this template letter is provided by Pfizer for informational purposes for patients who have been prescribed VYNDAMAX® (tafamidis).* 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.

<<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.[1]

*This sample letter of necessity can be modified to support coverage for VYNDAQEL® (tafamidis meglumine).

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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 judgment.]

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>>

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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,

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