Vyndamax® (tafamidis) 61 mg capsules

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®

Enroll your patient in VyndaLink, a patient support program designed to help patients navigate access to and reimbursement for VYNDAMAX once it has been prescribed.†

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

You can submit a PA request 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.

Pfizer Rare Disease

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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. Please note that 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 patient support program can assist patients with benefits verification and help determine when a PA is required and 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.

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

Physician Information

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

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

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Pfizer Rare Disease

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Consider including clinical documentation, for example:

- Date and method of ATTR-CM diagnosis, including ICD-10-CM code(s)
  - Date of ATTR-CM diagnosis
  - Diagnostic evaluation(s): *[e.g., the diagnostic evaluative steps used 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: *[e.g., 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
  - 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

Please ensure that all of the appropriate information is included in the PA request. The most common reasons for PA denial may include:

- Incorrect ICD-10-CM code(s) for ATTR-CM
- Lack of documentation supporting correct diagnosis

APPEALS CHECKLIST

If a 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

When submitting an appeal, the following information may be required:

Insurer Information:

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

Consider including clinical documentation, for example:

- ✓ A Letter of Medical Necessity (see example at the end of this document)
- ✓ Chart notes with medical and treatment history, including:
  - Date and method of ATTR-CM diagnosis, including ICD-10-CM code(s)
    - Date of ATTR-CM diagnosis
    - Diagnostic evaluation(s): *[e.g., the diagnostic evaluative steps used 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: *[e.g., 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
    - Intracardiac mechanical assist device(s)
  - Previous and/or current treatments
  - VYNDAMAX® (tafamidis)* full prescribing information, available at www.VyndamaxHCP.com
  - Summary of professional opinion of the patient's likely prognosis or disease progression without treatment with VYNDAMAX

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

SAMPLE LETTER OF MEDICAL NECESSITY

(Optional to accompany prior 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 be a substitution 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.[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.

*This sample letter of medical necessity can be modified for patients who have been prescribed VYNDAQEL® (tafamidis meglumine).

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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): *[e.g., the diagnostic evaluative steps used 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: *[e.g., 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
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- 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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