VyndaLink™
Connecting Access, Reimbursement, and Education

PRIOR AUTHORIZATION CHECKLIST

Insurers are likely to require a prior authorization (PA) before approving coverage for VYNDAMAX® (tafamidis) or tafamidis meglumine. It is the responsibility of the physician to prepare and submit a PA. Coverage criteria may vary, so it is important to review the individual guidelines for each insurer and medication. The **VyndaLink** support program or a network specialty pharmacy can assist patients with benefits verification and help determine when a PA is required and what the criteria are for coverage.

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 of insurer
- ✓ 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 (eg, 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
    - Serum free light-chain assay
  - If applicable, genetic testing and variant/wild-type determination
- ✓ 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 (eg, 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 walked)
- 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 of 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

The information contained in this document is provided by Pfizer for informational purposes for patients who have been prescribed VYNDAMAX or tafamidis meglumine. There is no requirement that any patient or healthcare provider use any Pfizer product in exchange for this information, and this document is not meant to substitute for a prescriber's independent medical decision making.

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Pfizer Rare Disease