



Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

DRUG POLICY

Attruby (acoramidis), Vyndaqel (tafamidis meglumine) Vyndamax (tafamidis)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Vyndaqel and Vyndamax policy is to encourage appropriate use according to product labeling, clinical guidelines, and clinical trials.

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Attruby, Vyndaqel, and Vyndamax are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

Note: Amvuttra (vutrisiran) is a transthyretin-directed small interfering RNA indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults and cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations, and urgent heart failure visits. Refer to the Amvuttra drug policy for drug specific criteria.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Biopsy proven disease:
 - Tissue biopsy confirming the presence of the transthyretin amyloid deposition
 - Immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy results confirming transthyretin precursor proteins
- Technetium-labeled bone scintigraphy proven disease:
 - Scintigraphy tracing results confirming presence of amyloid deposits
 - A serum kappa/lambda free light chain ratio, serum protein immunofixation or urine protein immunofixation test result showing the absence of monoclonal proteins
- Echocardiography or cardiac magnetic resonance imaging results confirming cardiac involvement
- For members with hereditary ATTR-CM: results confirming a mutation of the transthyretin (TTR) gene
- Medical records documenting NYHA classification of heart failure
- For continuation of therapy: Medical record documentation confirming the member demonstrates a beneficial response to treatment (e.g., improvement in rate of disease progression as demonstrated by distance walked on the 6-minute walk test, the Kansas City Cardiomyopathy Questionnaire–Overall Summary (KCCQ-OS) score, cardiovascular-related hospitalizations, NYHA classification of heart failure, left ventricular stroke volume, NT-proBNP level)

Criteria for Initial Approval

A.) Cardiomyopathy of Wild Type or Hereditary Transthyretin-mediated Amyloidosis

Authorization of 12 months may be granted for treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) when all of the following criteria are met:

1. Member does not have NYHA Class III or Class IV heart failure (see Appendix A)
2. For members with hereditary ATTR-CM, presence of a mutation of the TTR gene was confirmed
3. The diagnosis is confirmed by one of the following:
 - a. The member meets both of the following:
 - i. Presence of transthyretin amyloid deposits on analysis of biopsy from cardiac or noncardiac sites (e.g., fat aspirate, gastrointestinal sites, salivary glands, bone marrow)
 - ii. Presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy
 - b. The member meets both of the following:
 - i. Positive ^{99m}technetium-labeled bone scintigraphy tracing
 - ii. Light chain amyloidosis has been ruled out by a test showing absence of monoclonal proteins (serum kappa/lambda free light chain ratio, serum and urine protein electrophoresis with immunofixation)
4. Cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 mm)
5. The member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)
6. The requested medication will not be used in combination with another transthyretin stabilizer, or with inotersen (Tegsedi), patisiran (Onpattro), vutrisiran (Amvuttra), or eplontersen (Wainua)
7. The medication is being prescribed by or in consultation with a cardiologist

Continuation of Therapy

Authorization of 12 months may be granted for the continued treatment of ATTR-CM when all of the following criteria are met:

1. The member must have met all initial authorization criteria.
2. The member must have demonstrated a beneficial response to treatment with therapy (e.g., improvement in rate of disease progression as demonstrated by distance walked on the 6-minute walk test, the Kansas City Cardiomyopathy Questionnaire–Overall Summary [KCCQ-OS] score,

cardiovascular-related hospitalizations, NYHA classification of heart failure, left ventricular stroke volume, N-terminal B-type natriuretic peptide [NT-proBNP] level). Documentation from the medical record must be provided.

Other

Attruby, Vyndaqel and Vyndamax are considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

- Attruby 120 tablets per 30 days
- Vyndaqel 120 capsules per 30 days
- Vyndamax 30 capsules per 30 days

Appendix

Appendix A. New York Heart Association (NYHA) Functional Classification

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, and dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Vyndaqel and Vyndamax [package insert]. New York, NY: Pfizer Labs.; October 2023.
- Attruby [package insert]. Palo Alto, CA: BridgeBio Pharma, Inc.; November 2024.
- Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018 Sep 13; 379(11):1007-1016.
- Witteles RM, Bokhari S, Damy T, et al. Screening for transthyretin amyloid cardiomyopathy in everyday practice. J Am Coll Cardiol HF. 2019 Aug, 7(8):709-716.
- Kittleson MM, Ruberg FL, Ambardekar AV, et al. 2023 ACC expert consensus decision pathway on comprehensive multidisciplinary care for the patient with cardiac amyloidosis: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023; Epublished DOI: 10.1016/j.jacc.2022.11.022

- Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145:e895-e1032.
- Maurer MS, Sabahat B, Thibaud D, et al. Expert consensus recommendations for the suspicion and diagnosis of transthyretin cardiac amyloidosis. *Circ Heart Fail*. 2019 Sep 4;12:9.
- Ruberg FL, Grogan M, et al. Transthyretin amyloid cardiomyopathy. *J Am Coll Cardiol*. 2019;73:2872-91.
- Yadav JD, Othee H, Chan KA, Man DC, Belliveau PP, Towle J. Transthyretin Amyloid Cardiomyopathy- Current and Future Therapies. *Ann Pharmacother*. 2021;55(12):1502-1514.
- Gillmore JD, Judge DP, Cappelli F, et al. Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy. *N Engl J Med*. 2024;390(2):132-142.

*Some content reprinted from CVS Caremark.

POLICY HISTORY

Policy #: 05.02.79

Original Effective Date: October 22, 2019

Reviewed: April 2026

Revised: January 2025

Current Effective Date: March 21, 2025