Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Attruby™ (acoramidis)

Effective: May 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Attruby (acoramidis) is a transthyretin stabilizer indicated for the treatment of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Attruby for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of wild type or hereditary (variant) transthyretin amyloid cardiomyopathy, confirmed by **one (1)** of the following:
    a. Cardiac scintigraphy with technetium-99m-labeled bone-seeking
    b. Endomyocardial biopsy
    c. Genetic testing

AND

2. Documentation demonstrating the absence of monoclonal protein in serum and urine, obtained through laboratory work, to rule out light chain amyloidosis cardiomyopathy

AND

3. Documentation of diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) demonstrating cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum)

AND

4. The patient is at least 18 years of age or older

AND

5. Prescribed by or in consultation with a cardiologist

AND

6. Documentation the patient has New York Heart Association (NYHA) functional class I, II, or III of heart failure

AND

7. Documentation of **one (1)** of the following:
    a. The patient has not had a prior cardiac or liver transplant
    b. Evidence of amyloid deposits post cardiac or liver transplantation

AND

8. Documentation the requested medication will not be used concomitantly with another medication indicated for the

management of cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (e.g., Amvuttra, Onpattro, Tegsedi, Vyndamax/Vyndagel, Wainua)

Reauthorization Criteria

1. Documented diagnosis of wild type or hereditary (variant) transthyretin amyloid cardiomyopathy

AND

2. Documentation demonstrating the absence of monoclonal protein in serum and urine, obtained through laboratory work, to rule out light chain amyloidosis cardiomyopathy

AND

3. Documentation of diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) demonstrating cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum)

AND

4. The patient is at least 18 years of age

AND

5. Prescribed by or in consultation with a cardiologist

AND

6. Documentation the patient has New York Heart Association (NYHA) functional class I, II, or III of heart failure

AND

7. Documentation of **one (1)** of the following:
    a. The patient has not had a prior cardiac or liver transplant
    b. Evidence of amyloid deposits post cardiac or liver transplantation

AND

8. Documentation the requested medication will not be used concomitantly with another medication indicated for the management of cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (e.g., Amvuttra, Onpattro, Tegsedi, Vyndamax/Vyndagel, Wainua)

AND

9. Documentation the patient has experienced a positive therapeutic response as evidenced by **one (1)** of the following:
    a. Improvement in the distance walked on the 6-minute walk test (6MWT) as compared to baseline
    b. Decreased number of cardiovascular-related hospitalizations
    c. Improvement in Kansas City Cardiomyopathy Questionnaire & Overall Summary (KCCQ-OS) score
    d. Clinical improvement in symptoms or slowing of disease progression

Limitations

1. Initial coverage of a Attruby will be authorized for six (6) months. Reauthorization of Attruby will be provided for 12-month intervals,
2. Members new to the plan stable on Attruby should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Gertz MA, et al. Diagnosis, prognosis, and therapy of transthyretin amyloidosis. J Amer Coll of Cardiology. 2015 Dec;66(21) 2451-66.
2. Gilmore JD, et al. Efficacy and safety of acoramidis in transthyretin amyloid cardiomyopathy. N Engl J Med. 2024;390(2):132–142.
3. Ji AX, et al. Acoramidis produces near-complete TTR stabilization in blood samples from patients with variant transthyretin amyloidosis that is greater than that achieved with tafamidis. Poster presented at: The 2023 European Society of Cardiology Meeting; August 25–28, 2023; Amsterdam, The Netherlands.
4. Ruberg FL, Grogan M, Hanna M, et al. Transthyretin amyloid cardiomyopathy. J Amer Coll Cardiology. 2019;73(22):2872-91.
5. Kittleson MM, et al. Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement From the American Heart Association. Circulation. 2020 June
6. Attruby (acoramidis) [prescribing information]. Palo Alto, CA: BridgeBio Pharma, Inc.; November 2024.

Approval And Revision History

April 8, 2025: Reviewed by the Pharmacy & Therapeutics Committee.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.