Clinical Policy: Acoramidis (Attruby)

Reference Number: PA.CP.PHAR.683
Effective Date: 02/2025
Last Review Date: 07/2025

Description
Acoramidis (Attruby™) is a transthyretin stabilizer.

FDA Approved Indication(s)
Attruby is indicated for the treatment of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Attruby is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Transthyretin Amyloid Cardiomyopathy (must meet all)**:**

1. Diagnosis of ATTR-CM as supported by one of the following (a or b):
   a. Tissue biopsy amyloid protein is identified as transthyretin via mass spectrometry or immunohistochemistry, and (i):
      i. Tissue biopsy is of endomyocardial origin;
   b. Member meets all of the following (i, ii, and iii):
      i. Echocardiography (Echo), cardiac magnetic resonance imaging (CMR), or positron emission tomography (PET) findings are consistent with cardiac amyloidosis;
      ii. Cardiac uptake is Grade 2 or 3 on a radionuclide scan utilizing one of the following radiotracers (1, 2, or 3):
         1) 99m technetium (Tc)-labeled 3,3-diphosphono-1,2-propanodicarboxylic acid (DPD);
         2) 99mTc-labeled pyrophosphate (PYP);
         3) 99mTc-labeled hydroxymethylene diphosphonate (HMDP);
      iii. Each of the following laboratory tests is negative for monoclonal protein (1, 2, and 3):
         1) Serum kappa/lambda free light chain ratio analysis;
         2) Serum protein immunofixation;
         3) Urine protein immunofixation;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;
4. Member has heart failure of New York Heart Association (NHYA) Class I, II, or III;
5. Member has one of the following (a or b):
   a. At least 1 prior hospitalization for heart failure;

b. Current (within the last 30 days) clinical evidence of heart failure (i.e., signs and symptoms, see *Appendix D*);

6. Attruby is not prescribed concurrently with Vyndaqel®/Vyndamax™, Onpattro®, Amvuttra®, or Wainua™;
7. Dose does not exceed 1,424 mg (4 tablets) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Transthyretin Amyloid Cardiomyopathy (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by, including but not limited to improvement or stabilization in any of the following parameters:
   a. Walking ability;
   b. Cardiac related hospitalization;
   c. Cardiac procedures or laboratory tests (e.g., Holter monitoring, echocardiography, electrocardiogram, plasma BNP or NT-proBNP, serum troponin);
3. Attruby is not prescribed concurrently with Vyndaqel/Vyndamax, Onpattro, Amvuttra, or Wainua;
4. If request is for a dose increase, new dose does not exceed 1,424 mg (4 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ATTR-CM: transthyretin amyloidosis cardiomyopathy

CMR: cardiac magnetic resonance imaging

DPD: 99Tc-labeled 3,3-diphosphono-1,2-propanodicarboxylic acid
Echo: echocardiography
FDA: Food and Drug Administration
HF: heart failure
HMDP: 99mTc-labeled hydroxymethylene diphosphonate
NHYA: New York Heart Association
PET: positron emission tomography
PYP: 99mTc-labeled pyrophosphate
Tc: technetium

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- While signs and symptoms of advanced heart failure are variable, common manifestations of advanced heart failure include exercise intolerance, unintentional weight loss, refractory volume overload, recurrent ventricular arrhythmias, as well as hypotension and signs of inadequate perfusion (e.g., low or narrowed pulse pressure, cool extremities, and mental status changes). Laboratory testing that may reveal signs of advanced heart failure includes indications of poor or worsening renal function, hyponatremia, hypoalbuminemia, congestive hepatopathy, and elevated serum natriuretic peptide levels. Pulmonary edema, pleural effusions, and/or pulmonary vascular congestion on chest radiograph are also suggestive of advanced heart failure.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ATTR-CM	712 mg PO BID	1,424 mg/day

VI. Product Availability
Tablet: 356 mg

VII. References
1. Attruby Prescriber Information. Palo Alto, CA; BridgeBio Pharma, Inc.; November 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216540s000lbl.pdf. Accessed April 17, 2025.
2. ClinicalTrials.gov. Efficacy and Safety of AG10 in Subjects with Transthyretin Amyloid Cardiomyopathy (ATTRibute-CM). Available at: https://clinicaltrials.gov/study/NCT03860935. Accessed May 23, 2025.
3. Gillmore JD, Judge DP, Cappelli F, et al. Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy. N Engl J Med. 2024 Jan 11;390(2):132-142. doi: 10.1056/NEJMoa2305434.
4. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013; 8:31.
5. Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016;133(24):2404. Epub 2016 Apr 22.

6. Dorbala S, Ando Y, Bokhari S, et al. ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI expert consensus recommendations for multimodality imaging in cardiac amyloidosis: Part 1 of 2 - Evidence base and standardized methods of imaging. J Cardiac Failure; 2019: 24(11): e2-e39.
7. Dorbala S, Ando Y, Bokhari S, et al. ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI expert consensus recommendations for multimodality imaging in cardiac amyloidosis: Part 2 of 2- Diagnostic criteria and appropriate utilization. Journal of Cardiac Failure; 2019: 25(11): 854-865.
8. Witteles RM, Bokhari S, Damy T, et al. Screening for transthyretin amyloid cardiomyopathy in everyday practice. JACC, August 2019; 7(8): 709-16.
9. Kittleson MM, Maurer MS, Ambardekar AV, et al. Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement From the American Heart Association. Circulation; 2020 July: 142 (1): e7-e22.

Reviews, Revisions, and Approvals	Date
Policy created	01/2025
3Q 2025 annual review: no significant changes; references reviewed and updated.	07/2025