HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Attruby (acoramidis)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Attruby, approved by the FDA in 2024, is a transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization. Stabilizing TTR slows the formation of amyloid.
ATTR is a rare disease in which the transport protein transthyretin (TTR) is unstable and misfolds, accumulating as amyloid fibrils in the body. In the cardiomyopathy form of ATTR (ATTR-CM), the amyloid accumulates in the myocardium, resulting in heart failure. The hereditary form of ATTR (hATTR) is caused by a mutation in the TTR gene, whereas wild type ATTR (ATTRwt) is associated with aging.

Attruby (acoramidis) will be considered for coverage when the following criteria are met:

Transthyretin Amyloid Cardiomyopathy (ATTR-CM)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a cardiologist; AND
3. Member has a documented diagnosis of ATTR-CM confirmed by one of the following (a or b):
   a) Endomyocardial biopsy showing amyloidosis, with confirmatory TTR amyloid typing (by immunohistochemistry and/or mass spectrometry)
   b) Both of the following:
      i) Positive technetium-99m (99mTc) bone scintigraphy scan (Perugini grade 2 or 3 myocardial uptake), and
      ii) Absence of monoclonal light chains (based on both immunofixation electrophoresis (IFE) of serum and urine, and serum free light chain (sFLC) analysis); AND
4. Member has left ventricular (LV) wall thickness ≥ 12 mm (measured by ECHO or CMR); AND
5. Member has a history of heart failure (HF) with at least one of the following:
   a) At least 1 previous hospitalization for HF
   b) Signs and symptoms of volume overload or elevated intracardiac pressures
   c) HF symptoms that resulted in diuretic treatment; AND
6. Member has New York Heart Association (NYHA) Class I-III (not class IV) symptoms due to ATTR-CM; AND
7. Attruby will NOT be used in combination with another TTR stabilizer or a TTR silencer.
8. **Dosage allowed/Quantity limit:** 712 mg (2 tablets) orally twice daily.
   QL: 112 tablets per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document a positive clinical response to therapy such as stabilized or improved functional capacity (e.g., distance walked on 6-minute walk test [6MWT]), reduced cardiovascular-related hospitalizations, or improved quality of life score.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Attruby (acoramidis) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/19/2024	New policy for Attruby created.

References:

1. Attruby [prescribing information]. BridgeBio Pharma, Inc.; 2024.
2. 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. doi:10.1056/NEJMoa2305434
3. 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 [published correction appears in J Am Coll Cardiol. 2023 Apr 18;81(15):1551. doi: 10.1016/j.jacc.2023.03.002]. *J Am Coll Cardiol*. 2022;79(17):e263-e421. doi:10.1016/j.jacc.2021.12.012
4. 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 [published correction appears in J Nucl Cardiol. 2021 Aug;28(4):1763-1767. doi: 10.1007/s12350-021-02712-9]. *J Nucl Cardiol*. 2020;27(2):659-673. doi:10.1007/s12350-019-01761-5
5. 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 [published correction appears in J Nucl Cardiol. 2021 Aug;28(4):1761-1762. doi: 10.1007/s12350-021-02711-w]. *J Nucl Cardiol*. 2019;26(6):2065-2123. doi:10.1007/s12350-019-01760-6
6. Brito D, Albrecht FC, de Arenaza DP, et al. World Heart Federation Consensus on Transthyretin Amyloidosis Cardiomyopathy (ATTR-CM). *Glob Heart*. 2023;18(1):59. Published 2023 Oct 26. doi:10.5334/gh.1262
7. Wasfy JH, Winn AN, Touchette DR, Nikitin D, Shah KK, Richardson M, Lee W, Kim S, Rind DM. Disease Modifying Therapies for the Treatment of Transthyretin Amyloid Cardiomyopathy; Final Evidence Report. Institute for Clinical and Economic Review, October 21, 2024. https://icer.org/assessment/transthyretinamyloid-cardiomyopathy-2024

Effective date: 07/01/2025
Revised date: 12/19/2024