Effective date: 8/1/2025
Reviewed: 05/2025
Scope: Medicaid

ATTRUBY (acoramidis)

POLICY

I. INDICATIONS

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

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Cardiomyopathy of Wild Type or Variant/Hereditary Transthyretin-mediated Amyloidosis
Authorization of 6 months may be granted for treatment of cardiomyopathy of wild type or variant/hereditary transthyretin-mediated amyloidosis (ATTR-CM) when all of the following criteria are met:

A. Attruby is prescribed by, or in consultation with, a cardiologist.
B. Member is 18 years of age or older.
C. Documentation that the member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) classified as New York Heart Association (NYHA) class I, II, or III disease.
D. Documentation that cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 mm).
E. The diagnosis is confirmed by one of the following:
    1. The member has documentation that meets both of the following:
        i. Presence of transthyretin amyloid deposits on analysis of biopsy from cardiac or noncardiac sites.
        ii. Presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy.
    2. The member has documentation that meets both of the following:
        i. Positive technetium-labeled bone scintigraphy tracing.
        ii. Systemic light chain amyloidosis is ruled out by a test showing absence of monoclonal proteins (serum kappa/lambda free light chain ratio, serum protein immunofixation, or urine protein immunofixation).
F. Documentation of genetic testing which confirms the presence of a mutation of the TTR gene for members with variant/hereditary ATTR (hATTR)
G. The member is not a liver transplant recipient.
H. The requested medication will not be used in combination with patisiran (Onpattro), vutisiran (Amvuttra), eplontersen (Wainua), or tafamidis (Vyndaqel/Vyndamax)
I. If the request is for Attruby to be used in combination with a TTR-silencer/reducer (e.g., patisiran (Onpattro), eplontersen (Wainua)) to treat overlapping ATTR-CM and ATTR-PN, the member has a documented inadequate response, intolerance, or contraindication to monotherapy vutisiran (Amvuttra)

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for the continued treatment of ATTR-CM when all of the following criteria are met:

A. Documentation that the member must meet all initial authorization criteria.
B. Documentation (e.g., medical records, chart notes) that the member must have demonstrated a beneficial response to treatment with acoramidis 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, left ventricular stroke volume, N-terminal B-type natriuretic peptide (NT-proBNP) level].
C. Documentation that the member has not progressed to NYHA class IV disease.

V. QUANTITY LIMIT

Attruby 356 mg pak has a quantity limit of 4 tablets per day.

VI. REFERENCES

1. Attruby [package insert]. Palo Alto, CA: BridgeBio Pharma, Inc.; November 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.
3. Ruberg FL, Grogan M, Hanna M, et al. Transthyretin amyloid cardiomyopathy: JACC State-of-the-Art Review. J Am Coll Cardiol. 2019;73(22):2872-2891.
4. Yadav JD, Othee H, Chan KA, et al. Transthyretin Amyloid Cardiomyopathy-Current and Future Therapies. Ann Pharmacother. 2021;55(12):1502-1514.
5. Maurer MS, Sabahat B, Thibaud D, et al. Expert consensus recommendations for the suspicion and diagnosis of transthyretin cardiac amyloidosis. Circ Heart Fail. 2019;12(9):e006075.