

# Specialty Guideline Management

## Attruby

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Attruby	acoramidis

### 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<sup>1</sup>

Attruby is 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.

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

### Documentation

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

## Initial requests

- Chart notes or medical record documentation confirming the member demonstrates clinical symptoms of cardiomyopathy and heart failure
- For 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
- For 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
- For variant ATTR-CM: results confirming a mutation of the transthyretin (TTR) gene

## Continuation requests

Chart notes or 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, New York Heart Association [NYHA] classification of heart failure, left ventricular stroke volume, N-terminal B-type natriuretic peptide [NT-proBNP] level)

## Coverage Criteria

### Cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis<sup>1-5</sup>

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

- The member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema).
- The diagnosis is confirmed by either of the following criteria:
  - The member meets both of the following criteria:
    - Presence of transthyretin amyloid deposits on analysis of biopsy from cardiac or noncardiac sites.
    - Presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy.
  - The member meets both of the following criteria:

- Positive technetium-labeled bone scintigraphy tracing.
- 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).
- For members with variant ATTR-CM, presence of a mutation of the TTR gene was confirmed.
- The member is not a liver transplant recipient.
- The requested medication will not be used in combination with inotersen (Tegsedi), patisiran (Onpattro), vutrisiran (Amvuttra), eplontersen (Wainua), tafamadis meglumine (Vyndaqel), or tafamadis (Vyndamax).

## Continuation of Therapy

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

- The member must meet all requirements in the coverage criteria section.
- 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, NYHA classification of heart failure, left ventricular stroke volume, N-terminal B-type natriuretic peptide [NT-proBNP] level).

## 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.