Reference number(s)
6744-A

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[1]

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[1-5]

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.