

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2025 P 2362-1
Program	Prior Authorization/Medical Necessity
Medication	Attruby [™] (acoramidis)
P&T Approval Date	1/2025
Effective Date	4/1/2025

1. Background:

Attruby 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.

2. Coverage Criteria^a:

A. Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

1. Initial Authorization

- a. Attruby will be approved based on <u>all</u> of the following criteria:
 - (1) Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

-AND-

- (2) **One** of the following:
 - (a) Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

-OR-

(b) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

-OR-

- (c) <u>All</u> of the following:
 - i. Echocardiagram or cardiac magnetic resonance imaging suggestive of amyloidosis

-AND-

ii. Radionuclide imaging (^{99m}Tc-DPD, ^{99m}Tc-PYP, or ^{99m}Tc-HMDP) showing grade 2 or 3 cardiac uptake*

-AND-

iii. Absence of light chain amyloidosis

-AND-

(3) Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure

-AND-

(4) Physician attests that the patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM

-AND-

- (5) **One** of the following:
 - (a) History of heart failure, with at least one prior hospitalization for heart failure

-OR-

(b) Presence of signs and symptoms of heart failure (e.g., dyspnea, edema)

-AND-

(6) Prescribed by or in consultation with a cardiologist

-AND-

(7) Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

Authorization will be issued for 12 months.

2. Reauthorization

- a. Attruby will be approved based on all of the following criteria:
 - (1) Documentation that the patient has experienced a positive clinical response to Attruby (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

-AND-

(2) Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

-AND-



(3) Prescribed by or in consultation with a cardiologist

-AND-

(4) Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*May require prior authorization and notification

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

- 1. Attruby [package insert]. BridgeBio Pharma, Inc: Palo Alto, CA; November 2024.
- 2. Fontana, M. Cardiac amyloidosis: Epidemiology, clinical manifestations, and diagnosis. UpToDate. Dardas, T: UpToDate Inc. https://www.uptodate.com (Accessed on December 2, 2024).
- 3. Fontana, M. Cardiac amyloidosis: Treatment and prognosis. UpToDate. Dardas, T: UpToDate Inc. https://www.uptodate.com (Accessed on December 2, 2024).
- 4. Ruberg FL, Maurer MS. Cardiac Amyloidosis Due to Transthyretin Protein: A Review. JAMA 2024; 331:778.
- Kittleson, M, Ruberg, F. et al. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. JACC. 2023 Mar, 81 (11) 1076–1126.

Program	Prior Authorization/Medical Necessity - Attruby [™] (acoramidis)
Change Control	
1/2025	New program.