Attruby™ (acoramidis) 356 mg tablet

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Prior authorization and appeals checklists

The checklists below provide information and tips that may be useful when writing letters to obtain treatment authorization for Attruby™ or to appeal a decision from your patient's insurance plan if an authorization for Attruby is denied.

This is not an instructional guide, and information provided is not intended to be a substitute for, or an influence on, your independent medical judgment.

PRIOR AUTHORIZATION (PA)

When responding to a PA request, a plan-specific form is typically required. This form can be found on the insurer's website.

- ☐ **Complete a PA request form and include information, such as:**
  - ☐ Patient name, date of birth, and health insurance information
  - ☐ Patient diagnosis, using an appropriate ICD-10-CM code. Example codes*: **E85.4: organ-limited amyloidosis, E85.82: wild-type transthyretin-related (ATTR) amyloidosis,** and **E85.9: amyloidosis, unspecified**
  - ☐ Provider name and NPI
- ☐ **Compose a written letter demonstrating medical necessity of Attruby**
  - ☐ You may include a letter of medical necessity or exception with your PA submission. A sample letter is available for reference at ForgingBridges.com/resources
- ☐ **Prepare the PA package, complete with additional supporting documentation, which may include:**
  - ☐ Attruby Prescribing Information
  - ☐ Published data (eg, *New England Journal of Medicine* publication)
  - ☐ Clinical notes/medical records/test results (eg, genetic testing, scintigraphy, biopsy)
  - ☐ Any other relevant details, such as peer-to-peer review, that will help strengthen your clinical rationale for authorization of Attruby

Remember to follow up with your patient's insurance plan if you have not received a decision within 72 hours for patients with Medicare.

PA DENIAL APPEAL

A plan-specific form is typically required for an appeal submission. The insurer will provide the appeal form and will describe the timelines for the appeal in the PA denial letter.

For Medicare plans, you may refer to the *Annotated Sample Coverage Determination Request Form* found at ForgingBridges.com/resources.

- ☐ **Identify the reason for denial**
  - ☐ Check the denial letter from the insurance plan or the explanation of benefits, as the denial reason is often included there. If not included, request, in writing, the reason for the denial
- ☐ **Compose a written appeal letter**
  - ☐ A sample appeal letter is available for reference at ForgingBridges.com/resources
- ☐ **Prepare the appeal package, complete with additional supporting documentation**

  Documentation may include:
  - ☐ Attruby Prescribing Information
  - ☐ Published data (eg, *New England Journal of Medicine* publication)
  - ☐ Clinical notes/medical records/test results (eg, genetic testing, scintigraphy, biopsy)
  - ☐ Any other relevant details that will help strengthen your clinical rationale for appealing a denial of Attruby

For PA and appeals support, contact your **Field Reimbursement Manager**

Questions? Call ForgingBridges at
1-888-55-BRIDGE (1-888-552-7434)
Mon–Fri, 8 AM to 8 PM ET or visit **ForgingBridges.com**

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; NPI=National Provider Identifier.
*Example ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications.

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INDICATION

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

IMPORTANT SAFETY INFORMATION

Adverse Reactions

Diarrhea (11.6% vs 7.6%) and upper abdominal pain (5.5% vs 1.4%) were reported in patients treated with Attruby versus placebo, respectively. The majority of these adverse reactions were mild and resolved without drug discontinuation.

Discontinuation rates due to adverse events were similar between patients treated with Attruby versus placebo (9.3% and 8.5%, respectively).

Laboratory Tests

Mean increase in serum creatinine of 0.2 and 0.0 mg/dL and a mean decrease in eGFR of 8.2 and 0.7 mL/min/1.73 m^2 was observed in the adults with ATTR-CM treated with Attruby versus placebo, respectively, at Day 28 and then stabilized. These changes were reversible after treatment discontinuation.

Use in Specific Populations

Pregnancy & Lactation: There are no data on the use of Attruby in pregnant women. Animal data have not shown developmental risk associated with the use of Attruby in pregnancy. There are no available data on the presence of Attruby in either human or animal milk or the effects of the drug on the breastfed infant or maternal milk production.

Please see full Prescribing Information for Attruby at Attruby.com/PI.

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