**Sample letter of medical exception/necessity for AttrubyTM (acoramidis)**

This sample letter contains suggestions for the type of information to consider when a letter of medical exception or necessity to a patient’s insurance provider may be appropriate. Any letter of medical exception/necessity should be based on your medical judgment and discretion.

Use of any information suggested in this letter does not guarantee that the health plan will approve coverage, and it is not intended to be a substitute for, or an influence on, the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payer's specific requirements at that time.

Physician letterhead

Date

Attn: Insert health plan contact name Patient name: Insert patient name

Insert health plan name DOB: Insert patient’s date of birth

Insert health plan mailing address Policy number: Insert subscriber policy number

Group number: Insert subscriber group number

Claim number: Insert patient claim number

**RE: Request for authorization of AttrubyTM (acoramidis)**

Dear insert Medical Director reviewer/name of health plan contact,

I am writing as the treating physician of insert patient name to request approval for coverage of Attruby for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM).

**Overview of ATTR-CM**

ATTR-CM is a rare and fatal condition characterized by restrictive cardiomyopathy and progressive heart failure. In patients with ATTR-CM, transthyretin breaks down and forms amyloid fibrils, which build up in heart tissue and limit the heart’s ability to pump blood. With increasing amyloid deposits, the heart chambers progressively stiffen and weaken, leading to heart failure. Patients usually die within 3 to 5 years of receiving a diagnosis.1-4

Insert patient name is insert age years old and was initially diagnosed with ATTR-CM on insert date. Insert patient name has been under my care since insert date, and I have determined that treatment with Attruby is medically necessary for this patient.

Attruby has demonstrated near-complete in vitro transthyretin (TTR) stabilization based on 712 mg acoramidis dosing.The efficacy of Attruby was demonstrated in the ATTRibute-CM trial, a multicenter, international, randomized, double-blind, placebo-controlled study in 611 adult patients with wild-type or variant ATTR-CM5:

* The primary composite endpoint included all-cause mortality (ACM) and cumulative frequency of cardiovascular-related hospitalizations (CVH) over 30 months, analyzed hierarchically using the stratified Finkelstein-Schoenfeld (F-S) test. The F-S test demonstrated a statistically significant reduction (p=0.018) in ACM and cumulative frequency of CVH in the Attruby arm vs the placebo arm. At 30 months, more patients were alive on Attruby (81% vs 74%), and there were fewer CVH events (0.3 vs 0.6 per year)
* 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. Increase in serum creatinine and decrease in eGFR may occur within 4 weeks of starting Attruby and then stabilize. The laboratory changes were reversible after treatment discontinuation

Please refer to patient chart notes, including relevant medical history, and the Attruby Prescribing Information for additional data:

* Insert appropriate ICD-10-CM code
* Demonstrate that diagnosis of immunoglobulin light chain amyloidosis has been ruled out
* Diagnostic signs of ATTR-CM through radiographic imaging or cardiac biomarker tests
* Use of electronic implantable cardiac devices, such as pacemaker or cardioverter defibrillator
* Use of intracardiac mechanical assist device(s)
* ATTR-CM–related comorbidities
* Symptoms associated with ATTR-CM
* Functional status of your patient
* Current/previous therapies used for treating ATTR-CM and associated symptoms and patient’s response to these therapies
* ATTR-related hospitalizations
* Summary of patient’s disease progression and prognosis without treatment with Attruby based on your clinical discretion

In summary, treatment with Attruby for insert patient name is medically appropriate and necessary. Please also refer to the enclosed materials for additional supporting information on the efficacy, safety, and capacity for Attruby to improve outcomes for insert patient name.

If you have further questions, please contact my office at insert phone number. I look forward to receiving your timely response and coverage determination.

Sincerely,

Insert prescriber name and date

Insert NPI number

Insert prescriber contact information

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(Signature) (Date)

Enclosures: Examples: Attruby Prescribing Information, published data (eg, *New England Journal of Medicine* publication), clinical notes/medical records/test results (eg, genetic testing, scintigraphy, biopsy), and any other relevant details, such as a peer-to-peer review

**References: 1.** Maurer MS, Elliot P, Comenzo R, Semigran M, Rapezzi C. Addressing common questions encountered in the diagnosis and management of cardiac amyloidosis. *Circulation*. 2017;135(14):1357-1377. **2.** Maurer MS, Hanna M, Grogan M, et al. Genotype and phenotype of transthyretin cardiac amyloidosis: THAOS (Transthyretin Amyloid Outcome Survey). *J Am Coll Cardiol*. 2016;68(2):161-172. **3.** Transthyretinamyloidosis (ATTR-CM). Cleveland Clinic. Accessed November 12, 2024. https://my.clevelandclinic.org/health/diseases/17855-amyloidosis-attr. **4.** Eidos Therapeutics initiates ATTRibute-CM, a Phase 3 study of AG10 in ATTR-CM with registrational 12-month endpoint. Press release. BridgeBio Pharma, Inc; February 27, 2019. Accessed November 12, 2024**.** https://investor.bridgebio.com/news-releases/news-release-details/eidos-therapeutics-initiates-attribute-cm-phase-3-study-ag10 **5.** Attruby. Prescribing information. BridgeBio Pharma, Inc; 2024.

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