Submitting a coverage determination request for Attruby™

A coverage determination is any decision made by a Part D plan sponsor regarding coverage or payment for a prescription drug, such as for a prior authorization or other utilization management requirement (eg, step therapy), exception requests (eg, formulary, tiering, or quantity limit exceptions), or others.

The information in this resource provides tips for submitting a coverage determination request related to Attruby on behalf of your patient with Medicare Part D prescription drug coverage.

This resource is for informational purposes only and does not guarantee coverage of Attruby.
It is not intended to be a substitute for, or an influence on, the independent medical judgment of the healthcare provider.

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1

REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION

This form may be sent to us by mail or fax:

Address:
[Insert plan address(es)]

Fax Number:
[Insert plan fax number(s)]

You may also ask us for a coverage determination by phone at [insert plan telephone number] or through our website at [insert plan web address].

Who May Make a Request: Your prescriber may ask us for a coverage determination on your behalf. If you want another individual (such as a family member or friend) to make a request for you, that individual must be your representative. Contact us to learn how to name a representative.

Enrollee's Information

Enrollee's Name		Date of Birth
Enrollee's Address		
City	State	Zip Code
Phone	Enrollee's Member ID #	

Complete the following section ONLY if the person making this request is not the enrollee or prescriber:

Requestor's Name		
Requestor's Relationship to Enrollee		
Address		
City	State	Zip Code
Phone		

Representation documentation for requests made by someone other than enrollee or the enrollee's prescriber:

Attach documentation showing the authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or a written equivalent). For more information on appointing a representative, contact your plan or 1-800-Medicare.

2

Name of prescription drug you are requesting (if known, include strength and quantity requested per month):

1

You may use this Coverage Determination Request Form from CMS or write your own. Part D plan sponsors must accept any written request for a coverage determination. This form can be found at **https://www.cms.gov/medicare/appeals-grievances/prescription-drug/coverage-determinations** and may also be available through CoverMyMeds®

2

Fill in information about the prescription:

- Attruby™ (acoramidis) 356 mg
- 28-day supply (4 blister cards [112 tablets] in 1 carton)

CMS=Centers for Medicare and Medicaid Services.

Type of Coverage Determination Request

3 ☐ I need a drug that is not on the plan's list of covered drugs (formulary exception).*

☐ I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year (formulary exception).*

☐ I request prior authorization for the drug my prescriber has prescribed.*

4 ☐ I request an exception to the requirement that I try another drug before I get the drug my prescriber prescribed (formulary exception).*

☐ I request an exception to the plan's limit on the number of pills (quantity limit) I can receive so that I can get the number of pills my prescriber prescribed (formulary exception).*

☐ My drug plan charges a higher copayment for the drug my prescriber prescribed than it charges for another drug that treats my condition, and I want to pay the lower copayment (tiering exception).*

☐ I have been using a drug that was previously included on a lower copayment tier, but is being moved to or was moved to a higher copayment tier (tiering exception).*

☐ My drug plan charged me a higher copayment for a drug than it should have.

☐ I want to be reimbursed for a covered prescription drug that I paid for out of pocket.

***NOTE: If you are asking for a formulary or tiering exception, your prescriber MUST provide a statement supporting your request. Requests that are subject to prior authorization (or any other utilization management requirement), may require supporting information. Your prescriber may use the attached "Supporting Information for an Exception Request or Prior Authorization" to support your request.**

Additional information we should consider *(attach any supporting documents)*:

5 _____

_____

_____

_____

Important Note: Expedited Decisions

If you or your prescriber believe that waiting 72 hours for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 72 hours could seriously harm your health, we will automatically give you a decision within 24 hours. If you do not obtain your prescriber's support for an expedited request, we will decide if your case requires a fast decision. You cannot request an expedited coverage determination if you are asking us to pay you back for a drug you already received.

☐**CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 24 HOURS (if you have a supporting statement from your prescriber, attach it to this request).**

Signature:	**Date:**

3

Check this box if Attruby™ is not on formulary

4

Check this box if the plan sponsor requires a step through another therapy prior to use of Attruby

5

Provide your rationale for requesting the coverage determination for Attruby.

Consider including supporting documentation for your patient's diagnosis, such as results from genetic testing, scintigraphy, biopsy, and other information, based on your clinical discretion.

A Sample Letter of Medical Necessity & Exception is available at **ForgingBridges.com/resources**

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Supporting Information for an Exception Request or Prior Authorization

FORMULARY and TIERING EXCEPTION requests cannot be processed without a prescriber's supporting statement. PRIOR AUTHORIZATION requests may require supporting information.

☐ **REQUEST FOR EXPEDITED REVIEW: By checking this box and signing below, I certify that applying the 72 hour standard review timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.**

Prescriber's Information		
Name		
Address		
City	State	Zip Code
Office Phone	Fax	
Prescriber's Signature	Date	

Diagnosis and Medical Information		
Medication:	Strength and Route of Administration:	Frequency:
Date Started: ☐ **NEW START**	Expected Length of Therapy:	Quantity per 30 days
Height/Weight:	Drug Allergies:	

DIAGNOSIS – Please list all diagnoses being treated with the requested drug and corresponding ICD-10 codes. (If the condition being treated with the requested drug is a symptom e.g. anorexia, weight loss, shortness of breath, chest pain, nausea, etc., provide the diagnosis causing the symptom(s) if known)	**ICD-10 Code(s)**
Other RELEVANT DIAGNOSES:	**ICD-10 Code(s)**

DRUG HISTORY: (for treatment of the condition(s) requiring the requested drug)

DRUGS TRIED (if quantity limit is an issue, list unit dose/total daily dose tried)	**DATES of Drug Trials**	**RESULTS of previous drug trials FAILURE vs INTOLERANCE (explain)**

What is the enrollee's current drug regimen for the condition(s) requiring the requested drug?

6 Attruby™ (acoramidis) 356 mg 2 tablets by mouth twice daily

7 Include language, such as "To be determined (long term, as long as the patient benefits)"

8 28-day supply (4 blister cards [112 tablets] in 1 carton)

9 **Diagnosis:** transthyretin amyloid cardiomyopathy (ATTR-CM)

Example ICD-10-CM codes*:

- **E85.4:** organ-limited amyloidosis
- **E85.82:** wild-type transthyretin-related (ATTR) amyloidosis
- **E85.9:** amyloidosis, unspecified

10 Fill in this section if your patient has been on any other therapies for ATTR-CM

ICD-10-CM=*International Classification of Diseases, Tenths Revision, Clinical Modification.*

*Example ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications.

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.

DRUG SAFETY	
Any **FDA NOTED CONTRAINDICATIONS** to the requested drug?	☐ YES ☐ NO
Any concern for a **DRUG INTERACTION** with the addition of the requested drug to the enrollee's current drug regimen?	☐ YES ☐ NO
If the answer to either of the questions noted above is yes, please 1) explain issue, 2) discuss the benefits vs potential risks despite the noted concern, and 3) monitoring plan to ensure safety	
HIGH RISK MANAGEMENT OF DRUGS IN THE ELDERLY	
If the enrollee is over the age of 65, do you feel that the benefits of treatment with the requested drug outweigh the potential risks in this elderly patient?	☐ YES ☐ NO
OPIOIDS – (please complete the following questions if the requested drug is an opioid)	
What is the daily cumulative Morphine Equivalent Dose **(MED)**?	____ **mg/day**
Are you aware of other opioid prescribers for this enrollee? If so, please explain.	☐ YES ☐ NO
Is the stated daily MED dose noted medically necessary?	☐ YES ☐ NO
Would a lower total daily MED dose be insufficient to control the enrollee's pain?	☐ YES ☐ NO

RATIONALE FOR REQUEST

11 ☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g. toxicity, allergy, or therapeutic failure** [Specify below if not already noted in the DRUG HISTORY section earlier on the form: (1) Drug(s) tried and results of drug trial(s) (2) if adverse outcome, list drug(s) and adverse outcome for each, (3) if therapeutic failure, list maximum dose and length of therapy for drug(s) trialed, (4) if contraindication(s), please list specific reason why preferred drug(s)/other formulary drug(s) are contraindicated]

☐ **Patient is stable on current drug(s); high risk of significant adverse clinical outcome with medication change** A specific explanation of any anticipated significant adverse clinical outcome and why a significant adverse outcome would be expected is required – e.g. the condition has been difficult to control (many drugs tried, multiple drugs required to control condition), the patient had a significant adverse outcome when the condition was not controlled previously (e.g. hospitalization or frequent acute medical visits, heart attack, stroke, falls, significant limitation of functional status, undue pain and suffering),etc.

☐ **Medical need for different dosage form and/or higher dosage** [Specify below: (1) Dosage form(s) and/or dosage(s) tried and outcome of drug trial(s); (2) explain medical reason (3) include why less frequent dosing with a higher strength is not an option – if a higher strength exists]

☐ **Request for formulary tier exception** Specify below if not noted in the DRUG HISTORY section earlier on the form: (1) formulary or preferred drug(s) tried and results of drug trial(s) (2) if adverse outcome, list drug(s) and adverse outcome for each, (3) if therapeutic failure/not as effective as requested drug, list maximum dose and length of therapy for drug(s) trialed, (4) if contraindication(s), please list specific reason why preferred drug(s)/other formulary drug(s) are contraindicated]

12 ☐ **Other** (explain below)

Required Explanation _____

13 _____
_____
_____
_____
_____

11 Check this box if your patient is switching therapies for ATTR-CM

12 Check this box if your patient is new to therapy

13 Include rationale here for prescribing Attruby™ for your patient. Clinical input for this section can also be included as an attachment

IMPORTANT SAFETY INFORMATION (cont'd)

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.

For coverage determination 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**