RECORDATI RARE DISEASES INC.
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Dear Healthcare Provider,

The appeals process with most insurance plans often requires the submission of a Letter of Appeal. The purpose of this exemplar letter is to assist your office in developing a customized Letter of Appeal, which addresses the reasons CYSTADANE (betaine anhydrous for oral solution) was denied, as well as outline the medical justification for CYSTADANE therapy.

Please note - this letter exemplar should only be used as a guide. However, it is suggested that your Letter of Appeal include:

1. The reason(s) CYSTADANE therapy was denied,
2. Response or rebuttal to each reason CYSTADANE was denied, and
3. Supporting documentation (such as lab results) justifying the need for CYSTADANE if needed.

As you know, each patient will have their own unique and specific reasons for needing CYSTADANE therapy. In addition, each insurance plan may have their own rules and guidelines for approving CYSTADANE.

This sample letter and related information are provided for informational purposes only. It is the responsibility of the HCP and/or their office staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient. Recordati Rare Diseases (RRD) does not guarantee coverage or reimbursement for the product. There is no requirement that any patient or healthcare provider use any RRD product in exchange for this information, and this template is not meant to substitute for a prescriber's independent medical decision-making.

For full Prescribing Information and Instructions for Use, please go to www.CYSTADANE.com.

Sincerely,
The CYSTADANE Team
Phone: (888)-487-4703
Fax: (855)-813-2039

ON OFFICE LETTERHEAD INLCUDING PROVIDER NAME AND ADDRESS

Name

Address

Phone

Fax

CYSTADANE® (betaine anhydrous for oral solution)

Letter of Appeal

EXEMPLAR

(Date)

(Payer Name)

(Payer Address)

Patient Name: (Patient Name)

Patient Date of Birth: (Patient DOB)

Policy Number: (Policy Number)

Group Number: (Group Number)

Case Number: (Case Number)

Subject: Letter of Appeal regarding CYSTADANE® (betaine anhydrous for oral solution)

To Whom It May Concern:

I am writing to request an APPEAL of the decision to deny CYSTADANE for my patient (**Patient name**). (**Patient name**) has been diagnosed with (**diagnosis**) and requires treatment with CYSTADANE.

CYSTADANE (betaine anhydrous for oral solution) is a methylating agent indicated in pediatric and adult patients for the treatment of homocystinuria to decrease elevated homocysteine blood concentrations. Included within the category of homocystinuria are:

- Cystathionine beta-synthase (CBS) deficiency
- 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
- Cobalamin cofactor metabolism (cbl) defect

This patient has been receiving treatment with CYSTADANE since (**Treatment initiation date**) and had seen the following clinical outcomes: (**list outcomes**).

Our office received a denial for CYSTADANE on (**date**). In that denial, CYSTADANE was denied due to the following reasons:

1.
2.
3.

I disagree with this decision. In my clinical judgement, treatment with CYSTADANE is medically necessary due to the following reasons:

1.
2.
3.

I would appreciate your reconsideration of this denial and ask that you reverse your decision and approve CYSTADANE for (**patient name**).

My intended use of CYSTADANE for this patient is **(dose)**.

If you have any questions or wish to conduct a Peer to Peer discussion, feel free to contact me at (**enter phone number**).

Thank you for your time and consideration!
(**First and Last name, MD**)