Dear Healthcare Provider,

Recordati Access, Resources, and Engagement (R.A.R.E.), a patient and provider support program within Recordati Rare Diseases Inc. has developed an:

**Isturisa® (osilodrostat) Letter of Medical Necessity and Intent to Treat TEMPLATE**

The purpose of this template letter is to assist your office in developing a customized Letter of Medical Necessity which outlines the medical justification for Isturisa® therapy. Often, by submitting a Letter of Medical Necessity tailored around the history and current treatment needs of your patient, insurance plans may better understand the reasoning for Isturisa®.

Please note - this letter template should only be used as a guide. Each patient will have their own unique and specific reasons for needing Isturisa® therapy. In addition, each insurance plan may have their own rules and guidelines for approving Isturisa®.

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.ISTURISA.com.

Sincerely,

Recordati Access, Resources, and Engagement (R.A.R.E.) Team

Phone: (888) 855-RARE (7273)

Fax: (855) 813-2039



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PP-IST-US-0241v

**[ON OFFICE LETTERHEAD INCLUDING PROVIDER NAME AND ADDRESS]**

Isturisa® (osilodrostat)

**Letter of Medical Necessity and Intent to Treat**

**TEMPLATE**

**[Date]**

**[Insurance Name]**

**[Insurance Address]**

Patient Name: **[Patient Name]**

Patient Date of Birth: **[Patient DOB]**

Policy Number: **[Policy Number]**

Group Number: **[Group Number]**

Subject: Intent to Treat with Isturisa® (osilodrostat) tablets for oral use

To Whom It May Concern:

I am writing on behalf of my patient **[Patient Name]**, who has been diagnosed with Cushing’s disease. I am writing to support the treatment of **[Patient Name]** with Isturisa® tablets for oral use. Isturisa® is a cortisol synthesis inhibitor indicated for the treatment of adult patients with Cushing’s disease for whom surgery is not an option or has not been curative.1

Cushing’s disease:

Cushing’s disease is a rare endocrine disorder caused by excessive cortisol, a vital hormone that regulates metabolism, maintains cardiovascular function, and helps the body respond to stress.2

Summary of Patient’s Diagnosis:

* **[Description of lab tests, imaging, etc. that supports diagnosis of Cushing’s disease]**

Summary of Patient’s History:

* **[Description of symptoms]**
* **[Description of surgical procedures related to Cushing’s disease]**
* **[List of previous prescription medications related to Cushing’s disease and response]**
* **[If not previously mentioned, rationale for not using prescription medications that are requested by insurance plan]**
* **[List of tests needed before starting Isturisa (potassium and magnesium levels, baseline electrocardiogram)]**

Rationale for Treatment:

It is my medical opinion that initiating Isturisa® for **[patient’s name]** is appropriate and medically necessary at this time. My intended use of Isturisa® will be to initiate treatment orally twice daily. I will monitor cortisol levels as well as response to therapy. In addition, I will titrate the dose of Isturisa® as outlined in Section 2.2 of the approved Prescribing Information. In the Isturisa® Phase 3 pivotal LINC-3 study, a significantly higher proportion of patients with Cushing’s disease treated with Isturisa® maintained normal mean urinary free cortisol (mUFC) at the end of the 8-week randomized withdrawal period (week 34) versus placebo (86% vs 29%).1 Normalization of cortisol concentrations (or action at its receptors) is the primary objective in the treatment of patients with Cushing’s disease.3

I would appreciate your evaluation of this request and ask that you approve Isturisa®. If you have any questions or wish to conduct a Peer to Peer discussion, feel free to contact me at **[phone number]**.

Sincerely,

**[HCP Name and participating provider number]**

Enclosures: **[List of documentation described in above letter]**

References:

1. Isturisa® (osilodrostat) [prescribing information]. Bridgewater, NJ: Recordati Rare Diseases Inc.; 2020.
2. Pivonello, R et al. Cushing’s disease: the burden of illness. *Endocrine*. 2017; 56:10-18.
3. Nieman, L et al. Treatment of Cushing’s Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015; 100(8):2807-2831.



Dear Healthcare Provider,

Recordati Access, Resources, and Engagement (R.A.R.E.SM), a patient and provider support program within Recordati Rare Diseases Inc. has developed an:

**Isturisa® (osilodrostat) Letter of Appeal TEMPLATE**

In an effort to help make the Appeal process as smooth as possible, we have developed a Letter of Appeal template for Isturisa.

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

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

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

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

If you have any questions or require any further assistance, please contact your local Isturisa Account Manager or Recordati Access, Resources, and Engagement (R.A.R.E.) at (888) 855-RARE (7273).

Sincerely,

Recordati Access, Resources, and Engagement staff

 

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*ON OFFICE LETTERHEAD INLCUDING PROVIDER NAME AND ADDRESS*

*Name Address Phone Fax*

**Isturisa (osilodrostat) Letter of Appeal TEMPLATE**

(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 Isturisa (osilodrostat) tablets for oral use

To Whom It May Concern:

I am writing to request an APPEAL of the decision to deny Isturisa for my patient (Patient Name). (Patient name) has been diagnosed with Cushing’s disease. Isturisa is a cortisol synthesis inhibitor indicated for the treatment of adult patients

with Cushing’s disease for whom surgery is not an option or has not been curative.

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

1.

2.

3.

I disagree with this decision. In my clinical judgement, treatment with Isturisa is medically necessary due to the following reasons (answer each reason why Isturisa was denied):

1.

2.

3.

Cushing’s disease:

As you know, Cushing’s disease is a rare endocrine disorder caused by excessive cortisol, a vital hormone that regulates metabolism, maintains cardiovascular function, and helps the body respond to stress.

Treatment Plan:

My intended use of Isturisa will be to initiate treatment orally twice daily. I will monitor cortisol levels as well as response to therapy. In addition, I will titrate the dose of Isturisa as outlined in Section 2.2 of the approved Prescribing Information. Note, in the Phase 3 pivotal LINC-3 study, a significantly higher proportion of patients with Cushing’s disease treated with Isturisa maintained normal mean urinary free cortisol (mUFC) at the end of the 8-week randomized withdrawal period (week 34) versus placebo (86% vs 29%). Cortisol level control is the primary objective in the treatment of patients with Cushing’s disease.

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

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)