Payers may require prior authorization or supporting documentation to process and cover a claim for the requested therapy. A prior authorization allows the payer to review the reason for the requested therapy and to determine medical appropriateness. A patient-specific Letter of Medical Necessity will help to explain the physician's rationale and clinical decision-making in choosing a therapy. The following is a sample Letter of Medical Necessity that can be customized based on your patient's medical history and physical examination. Please note that some payers may have specific forms that must be completed in order to request prior authorization or to document medical necessity.

[Insert letterhead with physician's name and address]

Sample Format: Letter of Medical Necessity

[Insert Name of Medical Director]	Patient Name: [_____]
[Insurance Company]	Policy ID/Group
[Insurance Company Address]	Number: [_____]
[Insurance Company City, State, Zip Code]	Claim Number: [_____]

Dear **[Insurance Company]**,

I am writing to provide additional information to support my claim for the treatment of **[insert patient's name]** with Recorlev® (levoketoconazole) 150 mg tablets for **[insert diagnosis]**. In brief, treatment of **[insert patient's name]** with Recorlev is medically appropriate and necessary and should be a covered and reimbursed treatment.

Below, this letter outlines **[insert patient's name]**'s relevant medical history, prognoses, treatment history, and treatment rationale.

Summary of patient's history
[You may want to include:]

- Documentation confirming diagnosis of Cushing's syndrome (ie, lab test results, imaging results, and chart notes such as urinary free cortisol, dexamethasone suppression test, adrenocorticotropic hormone, late-night salivary cortisol, and radiology reports)
- Documentation of surgical procedures related to Cushing's syndrome that the patient has undergone, including related chart notes, prior surgery notes, or surgeon consults
- Documentation of prescription medications related to Cushing's syndrome that the patient has received, including an explanation of inadequate results and/or why the patient is unable to take another medication for Cushing's syndrome
- Baseline electrocardiogram and liver function tests prior to initiating therapy
- Correction of hypokalemia and hypomagnesemia or documentation of normal levels

[Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for treatment

Level I evidence supports the use of levoketoconazole in the management of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative. Given that Recorlev is an FDA-approved treatment for endogenous hypercortisolemia in adult patients living with Cushing's syndrome, the published data supporting the use of Recorlev, and the patient's history and condition, I believe treatment with Recorlev for **[insert patient's name]** is warranted, appropriate, and medically necessary.[1]

Please call my office at **[insert telephone number]** if I can provide you with any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,
[Insert physician's name and participating provider number]

[Mandatory enclosures]
[Supporting documentation]
[Clinical notes]

[Suggested enclosures]
[Peer-reviewed literature]
[Package insert]

Reference: 1. Recorlev. Prescribing information. Xeris Pharmaceuticals, Inc; 2021.