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]**

## Letter of Medical Necessity Example

**[Insert Medical Director's Name]**
**[Insurance Company Name]**
**[Insurance Company Address]**
**[Insurance Company City, State, Zip code]**

Patient Name: [_____]
Policy ID/Group Number: [_____]
Claim Number: [_____]

Dear **[Insurance Company Name],**

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.

Please see Indication and Important Safety Information, including Boxed Warning for hepatotoxicity and QT prolongation, for RECORLEV on following pages.

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
- 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.[1] Given that Recorlev® is an FDA-approved treatment for endogenous hypercortisolemia in adult patients with Cushing's syndrome, the published data supporting use of Recorlev, and the patient's history and condition, I believe treatment with Recorlev of **[Insert Patient's Name]** is warranted, appropriate, and medically necessary.

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]**

## Indication

RECORLEV (levoketoconazole) is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

**Limitations of use:** RECORLEV is not approved for the treatment of fungal infections.

## Important Safety Information

**WARNING: HEPATOTOXICITY AND QT PROLONGATION**

- **Cases of hepatotoxicity with fatal outcome or requiring liver transplantation have been reported with oral ketoconazole. Some patients had no obvious risk factors for liver disease. RECORLEV is associated with serious hepatotoxicity. Evaluate liver enzymes prior to and during treatment**
- **RECORLEV is associated with dose-related QT interval prolongation. QT interval prolongation may result in life-threatening ventricular dysrhythmias such as torsades de pointes. Perform ECG and correct hypokalemia and hypomagnesemia prior to and during treatment**

- RECORLEV is contraindicated in patients:
  - With cirrhosis, acute liver disease or poorly controlled chronic liver disease, baseline AST or ALT >3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug-induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease
  - Taking drugs that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes
  - With prolonged QTcF interval >470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or long QT syndrome
  - With hypersensitivity to levoketoconazole, ketoconazole, or any excipient in RECORLEV
  - Taking certain drugs that are sensitive substrates of CYP3A4 or CYP3A4 and P-gp

Please see additional Important Safety Information on next page and full Prescribing Information, including Boxed Warning, for RECORLEV.

## Important Safety Information (Cont'd)

- RECORLEV may lead to hypocortisolism with a potential for life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary
- Hypersensitivity to RECORLEV has been reported. Anaphylaxis has been reported with oral ketoconazole
- RECORLEV may lower serum testosterone in men and women. Inform patients to report associated symptoms
- Most common adverse reactions are nausea/vomiting, hypokalemia, hemorrhage/contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain/dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia/sleep disturbances, and peripheral edema
- Avoid use of strong CYP3A4 inhibitors and inducers 2 weeks before and during RECORLEV treatment. Consult approved product labeling for drugs that are substrates of CYP3A4, P-gp, OCT2, and MATE prior to initiating RECORLEV. For atorvastatin, metformin, and gastric acid modulators, see full Prescribing Information for recommendations regarding concomitant use with RECORLEV
- Breastfeeding is not recommended during treatment and for one day after final dose

**Please see additional Important Safety Information on previous page and full Prescribing Information, including Boxed Warning, for RECORLEV.**

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

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

**Reference: 1.** Recorlev [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc.



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