RECORLEV® (levoketoconazole) Letter of Appeal TEMPLATE

***Please note- this template should only be used as a guide.**

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)

I. Summary of patient's diagnosis

I am writing to request an APPEAL of the decision to deny RECORLEV for my patient (patient name). (Patient name) has been diagnosed with Cushing's syndrome. RECORLEV 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. RECORLEV is not approved for the treatment of fungal infections.[1]

II. Denial reasons

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

1.
2.
3.

*Example topics to consider when an appeal is necessary:

- Surgical history – if the patient is not an appropriate candidate for surgery or has failed previous surgery
- Tried and failed previous medication
- If recommended therapy is not indicated for Cushing's syndrome
- Concerns with potential adverse reactions of recommended medication for this patient

The reasons for which you are denying coverage limits the access of RECORLEV for my patient. RECORLEV is an FDA-approved treatment for Cushing's syndrome and has demonstrated a favorable safety and efficacy profile in clinical trials.[1]

III. Response or Rebuttals to denied reasons

I disagree with this decision, in my clinical judgment, treatment with RECORLEV is medically necessary because of the following reasons:

1. *(correspond with denial reason #1)*
2. *(correspond with denial reason #2)*
3. *(correspond with denial reason #3)*

IV. Rationale for treatment/treatment plan

[Discuss rationale for using RECORLEV vs other treatments. Insert your recommendation summary here, including your professional opinion of your patient's likely prognosis or disease progression without treatment with product.]

If you have any questions or wish to conduct a peer-to-peer discussion, feel free to contact me at (phone number). Thank you for your time and consideration.

Sincerely,
[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.

Please see Important Safety Information on page 3 and full Prescribing Information, including Boxed Warning, for RECORLEV.

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
- 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 Medication Guide and full Prescribing Information, including Boxed Warning, for RECORLEV.

Reference: 1. RECORLEV [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; 2023.