

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 Appeal Letter - Formulary Exception will help to explain the physician's rationale and clinical decision-making in choosing a therapy. The following is a sample Appeal Letter - Formulary Exception 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]

Formulary Exception Example

[Date]

[Payer Name] [Payer
Address]

[Payer City, State, Zip Code]

ATTN: [Appeals Department]

RE: [Patient Name]
[Policy ID/Group Number]
[Date of Service]

To whom it may concern,

I am writing to request a formulary exception be granted for the treatment of [insert patient's name] with Recorlev[®] (levoketoconazole) 150 mg tablets for [insert diagnosis]. [Insert payer's name] does not include Recorlev on the approved formulary list.

Recorlev was approved by the US Food and Drug Administration in December 2021. Recorlev is a cortisol synthesis inhibitor that was systematically studied in patients with endogenous Cushing's syndrome.

Recorlev is 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

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

[Insert patient's name] is diagnosed with [insert patient's diagnosis]. I am a [insert physician's credentials], and I believe that Recorlev is the appropriate treatment. It is imperative that a formulary exception be made.

In my clinical judgment, treatment with Recorlev is medically necessary because [list the clinical justification(s) for the use of Recorlev].

I have enclosed additional documentation that supports this patient's need for treatment with Recorlev. In the best interest of my patient, I would appreciate your immediate review and ask that a formulary exception be granted. If you have further questions, please feel free to call me at [insert telephone number] to discuss.

Thank you in advance for your immediate attention to this request.

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

[Enclosures (suggested documents): Formulary Exception Request Form, if required (available on payer's website), original Prior Authorization Request Form, Denial Letter/ EOB, patient medical history, and other supporting documents]

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
- 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 [full Prescribing Information](#), including **Boxed Warning**, for RECORLEV.

Reference: 1. Recorlev [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc. Copyright © 2023-2025

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