**MEDICATION POLICY:**
# Recorlev (levoketoconazole)

**Applicable Drugs:** Recorlev (levoketoconazole)

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 2/27/2023

**Date Last Reviewed / Revised:** 5/21/2025

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

I. Documented diagnosis of the following condition AND must meet criteria listed under applicable diagnosis:
   A. Endogenous hypercortisolemia in patients with Cushing's syndrome where pituitary surgery is not an option or has not been curative and meets criteria 1 through 3:
      1. Documentation of baseline elevated 24 hour urinary free cortisol at least 1.5 X upper limit of normal
      2. Documentation of baseline laboratory testing, including liver function tests (LFTs) and electrocardiogram (ECG) prior to treatment initiation.
      3. Documented trial and failure of, intolerance to, or contraindication to oral ketoconazole.

II. Documentation verifying the patient is not on chronic glucocorticoid therapy.

III. Documented inability to maintain clinically stable 24-hour urinary free cortisol levels (i.e, below 1.5 x upper limit normal) with optimally dosed systemic ketoconazole.

IV. Minimum age requirement: 18 years old.

V. Recorlev is prescribed by, or in consultation with an endocrinologist.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

## EXCLUSION CRITERIA

- Diagnosis of pituitary or adrenal carcinoma
- Baseline alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 3 times the upper limit of normal
- Cirrhosis, acute liver disease or poorly controlled chronic liver disease, 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
- Prolonged QTcF interval > 470 ms at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or long QT syndrome
- Taking certain drugs that are sensitive substrates of CYP3A4 or CYP3A4 and P-gp

## Other Criteria

- Treatment is not approved for the treatment of fungal infections.

## Quantity / Days Supply Restrictions

- Quantities of up to 240 tablets per 30 days.

## Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 12 months: An updated letter of medical necessity or progress notes demonstrating effective therapy as evidenced by stable 24-hour urinary free cortisol levels (i.e., below 1.5 x ULN)

## Appendix

N/A

## References

1. Recorlev. Prescribing information. Xeris Pharmaceuticals, Inc.; 2023. Accessed May 21, 2025. https://www.recorlev.com/full-prescribing-information.pdf.
2. McCartney NK, Baker DE. Levoketoconazole. *Hosp Pharm.* 2022;57(5):605-614. doi: 10.1177/00185787221115368
3. Fleseriu M, Pivonello R, Elenkova A, et al. Efficacy and safety of levoketoconazole in the treatment of endogenous Cushing's syndrome (SONICS): a phase 3, multicentre, open-label, single-arm trial. *Lancet Diabetes Endocrinol.* 2019;7(11):855-865. doi: 10.1016/S2213-8587(19)30313-4.
4. Pivonello R, Zacharieva S, Elenkova A, et al. Levoketoconazole in the treatment of patients with endogenous Cushing's syndrome: a double-blind, placebo-controlled, randomized withdrawal study (LOGICS). *Pituitary.* 2022;25(6):911-926. doi: 10.1007/s11102-022-01263-7.
5. Simões Corrêa Galendi J, Correa Neto ANS, Demetres M, Boguszewski CL, Nogueira VDSN. Effectiveness of medical treatment of Cushing's disease: a systematic review and meta-analysis. *Front Endocrinol (Lausanne).* 2021;12:732240. doi: 10.3389/fendo.2021.732240.

6. Fleseriu M, Auchus R, Bancos I, et al. Consensus on diagnosis and management of Cushing's disease: a guideline update. *Lancet Diabetes Endocrinol*. 2021;9(12):847-875. doi: 10.1016/S2213-8587(21)00235-7.

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.