

Generic Name: Levoketoconazole

Applicable Drugs: Recorlev®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/27/2023

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV 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 urinary free cortisol.
 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. Minimum age requirement: 18 years old.
- IV. Treatment must be prescribed by or in consultation with an endocrinologist.

EXCLUSION CRITERIA

- Baseline alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 3 times the upper limit of normal.
- Prolonged QTcF interval > 470 ms at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or long QT syndrome.

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:** 1 year

- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Recorlev [package insert]. Xeris Pharmaceuticals, Inc.; Chicago, IL 60601; 2021.
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.