Recorlev (levoketoconazole)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Maintenance therapy requests: 1 year

Medications	Quantity Limit
Recorlev (levoketoconazole)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Recorlev (levoketoconazole) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Documentation is provided that individual is being treated for endogenous hypercortisolemia with Cushing's syndrome; **AND**
III. Diagnosis of Cushing's has been confirmed by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: 24-hour urinary free cortisol (UFC) test; Dexamethasone suppression test (DST); Late-night salivary cortisol (LNSC) test) that are indicative of a positive test;
IV. Documentation is provided that individual has had a trial of ketoconazole and experienced inadequate response (Nieman, 2015). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

V. One of the following:
    A. Disease persists or recurs following pituitary surgery; **OR**
    B. Pituitary surgery is not indicated or an option.

Recorlev (levoketoconazole) may not be approved for the following:

I. For the treatment of fungal infections; **OR**
II. Individual has cirrhosis, acute liver disease or poorly controlled liver disease; **OR**
III. Individual has recurrent symptomatic cholelithiasis; **OR**
IV. Individual has a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment; **OR**
V. Individual has extensive metastatic liver disease; **OR**
VI. Individual currently has baseline AST or ALT greater than 3 times the upper limit of normal; **OR**
VII. Individual is currently using CYP3A inducers (including but not limited to, rifampin, phenobarbital, phenytoin, carbamazepine) or CYP3A4 inhibitors (including but not limited to, diltiazem, verapamil, ritonavir, clarithromycin, nefazodone, itraconazole); **OR**

VIII. Individual is currently using agents or have co-morbid conditions which prolong the QT interval.

NOTE:
Recorlev (levoketoconazole) has a black box warning for hepatotoxicity and dose-related QT interval prolongation. Ketoconazole and Recorlev have similar Black Box Warnings regarding serious hepatotoxicity irrespective of the dosages used or the duration of treatment. No risk factors have been identified. Monitoring liver enzymes prior to and during treatment is recommended. Dose-related QT interval prolongation that may result in life threatening ventricular dysrhythmias such as torsades de pointes has been observed. Performing ECGs prior to and during treatment is recommended.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 7, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Nieman L, Biller B, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 100: 2807–2831, 2015. Available from: https://academic.oup.com/jcem/article/100/8/2807/2836065