PARAMOUNT
Affiliate of ProMedica

CRITERIA: PMT
APPROVED: 04/07/2022
VERIFIED: 06/15/2022
REVIEWED: 06/15/2022

Prior Authorization Criteria Form

This form applies to Paramount Commercial Members Only

Recorlev

Complete/review information, sign and date. Please fax signed forms to Paramount at **1-844-256-2025.** You may contact Paramount by phone at **1-419-887-2520** with questions regarding the Prior Authorization process. When conditions are met, we will authorize the coverage of Recorlev.

Brand Name (select from list of drugs shown)

Recorlev (levoketoconazole)

Quantity _____ Frequency _____ Strength_____
Route of Administration _____ Expected Length of Therapy _____

Patient Information

Patient Name: _____
Patient ID: _____
Patient Group No.: _____
Patient DOB: _____
Patient Phone: _____

Prescribing Physician

Physician Name: _____
Physician Phone: _____
Physician Fax: _____
Physician Address: _____
City, State, Zip: _____

Diagnosis: _____ ICD Code: _____

Comments: _____

Please circle the appropriate answer for each question.

1	Is the patient at least 18 years of age or older? [If no, no further questions.]	Yes	No
2	Does the patient have a diagnosis of endogenous hypercortisolemia with Cushing's Syndrome for which surgery has not been curative or is not an option? *Note: Documentation is required for approval.* [If no, no further questions.]	Yes	No
3	Does the patient have a medical diagnosis of pituitary or adrenal carcinoma? [If yes, no further questions.]	Yes	No
4	Does the patient have a medical history of any of the following: cirrhosis, acute liver disease or poorly controlled chronic liver disease, recurrent symptomatic	Yes	No

	cholelithiasis, extensive metastatic liver disease, or drug induced liver injury due to azole therapy requiring discontinuation of treatment? [If yes, no further questions.]		
5	Has the patient completed baseline liver tests (ALT, AST, bilirubin) that resulted < 3 times the upper limit of normal and does the provider have a plan to monitor the patient's liver tests weekly for at least 6 weeks, then every 2 weeks for the next 6 weeks, then monthly for the next 3 months and then as clinically indicated for the duration of treatment? *Note: Documentation is required for approval.* [If no, no further questions.]	Yes	No
6	Does the patient have a medical history of any of the following: Torsades de pointes, ventricular tachycardia, ventricular fibrillation, or long QT syndrome (including first-degree family history)? [If yes, no further questions.]	Yes	No
7	Has the patient completed a baseline electrocardiogram (ECG) that resulted in a QTcF interval <470 msec and does the provider have a plan to monitor the patient's ECG before each dose increase and then as clinically indicated for the duration of treatment? *Note: Documentation is required for approval.* [If no, no further questions.]	Yes	No
8	Are the patient's potassium and magnesium levels appropriate to initiate therapy (Hypokalemia and hypomagnesemia should be corrected prior to initiation of therapy)? *Note: Documentation is required for approval.* [If no, no further questions.]	Yes	No
9	Has the patient been screened and counseled for appropriate warnings, precautions, reproductive risks and drug interactions (QT prolonging drugs, CYP3A4, atorvastatin, metformin, gastric acid modulators, etc.) and have modifications to the treatment plan been made if necessary? [If no, no further questions.]	Yes	No
10	Has the patient been advised to NOT consume excessive amounts of alcohol while using Recorlev? [If no, no further questions.]	Yes	No
11	Has the patient tried and failed for at least 3 months of therapy, had an intolerance, or has a contraindication to ketoconazole therapy? *Note: Documentation is required for approval.* [If no, no further questions.]	Yes	No
12	Will the prescribed dosage exceed 1200 mg total per day (600 mg twice daily)? [If yes, no further questions.]	Yes	No
13	Has the provider submitted the patient's baseline urinary free cortisol? *Note: Documentation is required for approval.* [If no, no further questions.]	Yes	No
14	Is the requested drug being prescribed by an endocrinologist or oncologist? [If no, no further questions.]	Yes	No
15	Is the request for continuation of therapy? [If no, no further questions.]	Yes	No

16	Did the patient experience unacceptable toxicity (e.g., severe hypersensitivity reactions, etc.) while taking the requested medication? [If yes, no further questions.]	Yes	No
17	Did the patient experience disease response as evidenced by a decrease in urinary free cortisol from baseline? *Note: Documentation is required for approval.*	Yes	No

I affirm that the information given on this form is true and accurate as of this date.

Prescriber (Or Authorized) Signature and Date