

Recorlev (levoketoconazole)

POLICY

I. CRITERIA FOR APPROVAL

An authorization of 6 months may be granted when all the following criteria are met:

- A. Patient is 18 years or older
- B. Medication is prescribed by, or in consultation with endocrinologist
- C. Patient has documented diagnosis of hypercortisolemia with Cushing syndrome and documentation of either of the following is provided:
 - a. Pretreatment 24-hour urine free cortisol (UFC) levels
 - b. One of the following if UFC level is not an appropriate measure due to the member's condition (e.g., renal insufficiency/failure, adrenal incidentaloma)
 - i. Pretreatment late-night salivary cortisol
 - ii. Pretreatment 1 mg overnight dexamethasone suppression test (DST)
 - iii. Pretreatment longer, low dose DST (2mg per day for 48 hours)
- D. Patient has either had surgery that was not curative OR for members who are not candidates for surgery
- E. The member has experienced a failure, contraindication or intolerance to ketoconazole and at least two alternatives (e.g., cabergoline, Signifor LAR, Lysodren)
- F. Documentation is submitted with a baseline QTc-interval less than or equal to 470 milliseconds
- G. Patient does not have a diagnosis of cirrhosis, acute liver disease or poorly controlled chronic liver disease, recurrent symptomatic cholelithiasis, or extensive metastatic liver disease
- H. Patient does not have a history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or prolonged QT syndrome

II. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members with an indication listed in Section I who are currently receiving the requested medication and who meet one of the following:

- A. Documentation showing a reduction in 24-hour urine free cortisol levels from baseline
- B. Documentation showing lower cortisol levels since the start of therapy per one of the following tests (if UFC is not an appropriate measure due to the member's condition):
 - 1. Late-night salivary cortisol
 - 2. 1mg overnight dexamethasone suppression test (DST)
 - 3. Low dose DST (2mg per day for 48 hours)
- C. Improvement in signs or symptoms of the disease

III. QUANTITY LIMIT

- Recorlev 150mg: 8 tablets per day

Effective Date:08/01/2022
Reviewed: 5/2022, 5/2023, 6/2024, 7/2025
Scope: Medicaid

IV. COVERAGE DURATION

- Initial coverage: 6 months
- Continuation of coverage: 6 months

V. REFERENCES

1. Recorlev [package insert]. Chicago, IL: Xeris Pharmaceuticals, Inc.; December 2024.
2. Nieman LK, Biller B, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100:2807-2831.
3. 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.