

Effective Date:08/01/2022
Reviewed: 5/2022, 5/2023
Scope: Medicaid

## 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., Isturisa, Lysodren, Signifor LAR, cabergoline);
- 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

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#### IV. COVERAGE DURATION

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

#### V. REFERENCES

- A. Recorlev [package insert]. Chicago, IL: Xeris Pharmaceuticals, Inc.; December 2021.
- B. 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.
- C. 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.