



## Commercial/Healthcare Exchange PA Criteria

*Effective: May 12, 2022*

**Prior Authorization:** Recorlev

**Products Affected:** Recorlev (levoketoconazole) oral tablets

**Medication Description:** Recorlev, a cortisol synthesis inhibitor, is indicated for the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative. Recorlev was approved through the 505(b)(2) pathway and as such relied upon existing safety and efficacy information for ketoconazole tablets to support approval. Recorlev contains levoketoconazole as the active ingredient. Levoketoconazole is the 2S, 4R-enantiomer derived from racemic ketoconazole.

**Covered Uses:** Treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative.

**Exclusion Criteria:**

1. Treatment of fungal infections

**Required Medical Information:**

1. Diagnosis
2. Medical History
3. Previous therapies tried and failed

**Prescriber Restriction:** Prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the treatment of endogenous Cushing's syndrome.

**Age Restriction:** 18 years of age and older

**Coverage Duration:** 12 months

**Other Criteria:**

**Initial Approval Criteria**

1. **Endogenous Cushing's Syndrome.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A. Patient has hypercortisolemia; **AND**
  - B. According to the prescriber, the patient is not a candidate for surgery or surgery has not been curative; **AND**
  - C. Patient has tried ketoconazole tablets

**Renewal Criteria:**

- A. Member has responded positively to the treatment as determined by the prescribing physician; **AND**
- B. Member has not experienced unacceptable toxicity from the drug

May 2022



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.

Page 1 of 2



**References:**

1. Recorlev tablets [prescribing information]. Chicago, IL: Xeris; January 2022.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	5/12/2022

