



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

|                   |                                  |
|-------------------|----------------------------------|
| Program Number    | 2024 P 1379-3                    |
| Program           | Prior Authorization/Notification |
| Medication        | Recorlev® (levoketoconazole)     |
| P&T Approval Date | 2/2022, 2/2023, 2/2024           |
| Effective Date    | 5/1/2024                         |

**1. Background:**

Recorlev (levoketoconazole) is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing’s syndrome for whom surgery is not an option or has not been curative.

*Limitations of Use:*

Recorlev is not approved for the treatment of fungal infections.

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Recorlev** will be approved based on **both** of the following criteria:

a. Diagnosis of endogenous hypercortisolemia associated with Cushing’s syndrome

**-AND-**

b. **One** of the following:

(1) Patient is not a candidate for surgery

**-OR-**

(2) Surgery has not been curative

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Recorlev** will be approved based on the following criterion:

a. Documentation of positive response to Recorlev therapy

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.



**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place

**4. References:**

1. Recorlev [Package Insert]. Chicago, IL: Xeris Pharmaceuticals, Inc.; May 2023.

| Program               | Prior Authorization/Notification - Recorlev (levoketoconazole)                    |
|-----------------------|-----------------------------------------------------------------------------------|
| <b>Change Control</b> |                                                                                   |
| 2/2022                | New program                                                                       |
| 2/2023                | Annual review with no changes to coverage criteria. Added state mandate footnote. |
| 2/2024                | Annual review with no changes to coverage criteria. Updated reference.            |