

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2026 P 1379-5
Program	Prior Authorization/Notification
Medication	Recorlev® (levoketoconazole)*
P&T Approval Date	2/2022, 2/2023, 2/2024, 2/2025, 2/2026
Effective Date	5/1/2026

**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.

\*Recorlev is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

**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.; June 2023.

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<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.
2/2025	Annual review with no changes to coverage criteria. Added exclusion footnote and updated reference.
2/2026	Annual review with no changes.