

**Recorlev (levoketoconazole)**  
**Effective 11/01/2025**

|                              |  |  |   |
|------------------------------|--|--|---|
| <b>Plan</b>                  | <input type="checkbox"/> MassHealth UPPL<br><input checked="" type="checkbox"/> Commercial/Exchange  | <b>Program Type</b>                        | <input checked="" type="checkbox"/> Prior Authorization<br><input type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Benefit</b>               | <input checked="" type="checkbox"/> Pharmacy Benefit<br><input type="checkbox"/> Medical Benefit     |  |   |
| <b>Specialty Limitations</b> | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. |  |   |
| <b>Contact Information</b>   | <b>Medical Benefit</b><br><b>Pharmacy Benefit</b>  | Phone: 833-895-2611<br>Phone: 800-711-4555 | Fax: 888-656-6671<br>Fax: 844-403-1029  |
| <b>Exceptions</b>            | N/A  |  |   |

### Overview

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. Recorlev is not approved for the treatment of fungal infections.

### Coverage Guidelines

Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted when all the following criteria are met:

- Member has a diagnosis of hypercortisolemia secondary to Cushing's disease
- Member meets ONE of the following:
  - Surgery (e.g., pituitary surgery, adrenal surgery) is not an option for the member
  - Surgery has not been curative
- Member is 18 years of age or older

### Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

- Documentation member has had a positive clinical response to therapy (e.g., reduction in baseline 24-hour urinary free cortisol level)

### Limitations

- Initial approvals will be granted for 6 months
- Reauthorizations will be granted for 12 months.
- The following quantity limits apply:

| Drug Name and Dosage Form | Quantity Limit    |
|---------------------------|-------------------|
| Recorlev tablet           | 8 tablets per day |

### References

- Recorlev (levoketoconazole) [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; June 2023.

**Review History**

07/20/22 – Reviewed and created for July P&T. Effective 09/01/2022

08/13/2025 – Reviewed and updated at August P&T. Updated initial criteria to remove specialist prescriber requirement. Updated reauthorization criteria to require documentation of positive clinical response to therapy. Effective 11/01/2025.

