CVS Caremark®

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| Reference number(s) |
| 5130-A |

# Specialty Guideline Management Recorlev

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Recorlev | levoketoconazole |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications1

Recorlev is 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. The safety and effectiveness of Recorlev for the treatment of fungal infections have not been established.

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

* For initial requests, pretreatment cortisol level as measured by one of the following tests:
  + Urinary free cortisol (UFC)
  + Late-night salivary cortisol (LNSC)
  + 1 mg overnight dexamethasone suppression test (DST)
  + Longer, low dose DST (2 mg per day for 48 hours)
* For continuation of therapy requests (if applicable), laboratory report indicating current cortisol level has decreased from baseline as measured by one of the following tests:
  + Urinary free cortisol (UFC)
  + Late-night salivary cortisol (LNSC)
  + 1 mg overnight dexamethasone suppression test (DST)
  + Longer, low dose DST (2 mg per day for 48 hours)

## Coverage Criteria

### Cushing’s Syndrome/Disease1-3

Authorization of 6 months may be granted for treatment of endogenous hypercortisolemia in adult members with Cushing’s syndrome/disease who have either had surgery that was not curative OR for members who are not candidates for surgery.

## Continuation of Therapy

### Cushing’s Syndrome/Disease1-3

Authorization of 12 months may be granted for members that meet one of the following criteria:

* Lower cortisol levels since the start of therapy per one of the following tests:
  + Urinary free cortisol (UFC)
  + Late-night salivary cortisol (LNSC)
  + 1 mg overnight dexamethasone suppression test (DST)
  + Longer, low dose DST (2 mg per day for 48 hours)
* Improvement in signs or symptoms of the disease

## References

1. Recorlev [package insert]. Chicago, IL: Xeris Pharmaceuticals, Inc.; June 2023.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing’s Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818
3. 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. doi:10.1016/S2213-8587(21)00235-7