CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Recorlev (levoketoconazole)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

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. It is an enantiomer derived from racemic ketoconazole and is a cortisol synthesis inhibitor. Recorlev has black box warnings for hepatotoxicity and QT prolongation.
Cushing's syndrome is a disorder of excess cortisol which can be of an exogenous cause, for example from taking glucocorticoids, or it can be endogenous. Endogenous Cushing's syndrome is rare, with the most common type being Cushing's disease, which is caused by a pituitary adenoma that secretes excess adrenocorticotropic hormone (ACTH), a hormone responsible for cortisol production.

Recorlev (levoketoconazole) will be considered for coverage when the following criteria are met:

Cushing's Syndrome

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has a diagnosis of endogenous Cushing's Syndrome (e.g., pituitary adenoma); AND
4. Chart notes must include documentation of elevated baseline urinary free cortisol (UFC); AND
5. Documentation that pituitary surgery was not curative, or surgery is not an option; AND
6. Member has had a trial and failure of ketoconazole for at least 2 months at the maximum tolerated dose; AND
7. Provider attests **ALL** of the following have been or will be assessed prior to treatment:
   a) Liver enzymes
   b) ECG
   c) Potassium, magnesium.
8. **Dosage allowed/Quantity limit:** Initiate at 150 mg orally twice daily; titrate according to package insert up to a max dose of 600 mg orally twice daily. Quantity limit: 240 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document a decrease in UFC compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Recorlev (levoketoconazole) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/23/2022	New policy for Recorlev created.
04/09/2025	Updated references; removed improved signs and symptoms from reauthorization criteria per not being studied in clinical trial; changed trial length from three-months to two-months at the maximum tolerated dose for steroidogenesis inhibitor per Fleseriu M (2021) et al; added provider attestation to monitoring parameters; removed exclusions from criteria.

References:

1. Recorlev. [prescribing information]. Xeris Pharmaceuticals, Inc.; 2023.
2. Fleseriu M, Pivonello R, Elenkova A, et al. Efficacy and safety of levoketoconazole in the treatment of endogenous Cushing's syndrome (SONICS): a phase 3, multicentre, open-label, single-arm trial [published correction appears in Lancet Diabetes Endocrinol. 2019 Nov;7(11):e22]. *Lancet Diabetes Endocrinol*. 2019;7(11):855-865. doi:10.1016/S2213-8587(19)30313-4
3. 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
4. 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
5. Castinetti F, Nieman LK, Reincke M, Newell-Price J. Approach to the Patient Treated with Steroidogenesis Inhibitors. *J Clin Endocrinol Metab*. 2021;106(7):2114-2123. doi:10.1210/clinem/dgab122
6. Castinetti F, Guignat L, Giraud P, et al. Ketoconazole in Cushing's disease: is it worth a try?. *J Clin Endocrinol Metab*. 2014;99(5):1623-1630. doi:10.1210/jc.2013-3628

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