

<b>Policy Name:</b>	<b>Recorlev (levoketoconazole)</b>	<b>Policy #:</b>	<b>3158P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Recorlev (levoketoconazole).

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Recorlev (levoketoconazole) under the pharmacy benefit when the following criteria have been met.

## Criteria

### 1. Coverage Criteria for Cushing’s Syndrome

- 1.1 Diagnosis of endogenous hypercortisolemia related to Cushing’s syndrome
- 1.2 Age 18 years or older
- 1.3 Ordered by or in consultation with an endocrinologist (doctor of hormone-related conditions)
- 1.4 Patient is not a candidate for surgery, or previous surgery has not been curative
- 1.5 Documented trial and failure of ketoconazole

### 2. Approval Period

- 2.1 Initial approval: 12 months
- 2.2 Reauthorization: 12 months with documented clinical benefit as evidenced by a decrease in urinary free cortisol levels from baseline

### 3. Managed Dose Limit

- 3.1 240 tablets per 30 days

## CPT Codes

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## HCPCS Codes

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## References

1. Recorlev (levoketoconazole) [prescribing information]. Chicago, IL: Xeris Pharmaceuticals Inc; June 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;7(11):e22]. Lancet Diabetes Endocrinol. 2019;7(11):855-865.
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; 100:2807.
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 Dec;9(12):847-875.

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