# Pharmacy Drug Policy & Procedure

| Policy Name: | Recorlev (levoketoconazole) | Policy #: | 3158P |
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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 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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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.