

Clinical Policy Title:	levoketoconazole
Policy Number:	RxA.750
Drug(s) Applied:	Recorlev®
Original Policy Date:	04/18/2022
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Endogenous Cushing's syndrome (must meet all):

1. Diagnosis of endogenous Cushing's syndrome;
2. Member is not a candidate for surgery, or previous surgery has not been curative;
3. Member does not have a diagnosis of pituitary or adrenal carcinoma;
4. Member meets the following (a and b):
 - a. Documentation of baseline urinary free cortisol;
 - b. Documentation of baseline liver enzyme function tests;
5. Trial and failure of ketoconazole unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Fleseriu M, Auchus RJ, Greenman Y, et al. Levoketoconazole treatment in endogenous Cushing's syndrome: extended evaluation of clinical, biochemical, and radiologic outcomes. *Eur J Endocrinol.* 2022;187(6):859-871. Published 2022 Nov 24. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9716395/>. Accessed September 4, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/08/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.6: Updated to remove requirement for documentation of baseline	03/29/2023	04/13/2023

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

urinary free cortisol and baseline liver enzyme function tests; 2. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage.	08/28/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025