



# Recorlev Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
12-15-2025

**Date of Origin**  
06-07-2022

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Recorlev	Levoketoconazole Tab	150 MG	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Recorlev	Levoketoconazole Tab	150 MG	240	Tablets	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Recorlev	Levoketoconazole Tab	150 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Recorlev	Levoketoconazole Tab	150 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. BOTH of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has a diagnosis of Cushing’s syndrome <b>AND</b> ALL of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient had an inadequate response to surgery <b>OR</b></li> <li>2. The patient is NOT a candidate for surgery <b>AND</b></li> </ol> </li> <li>B. ONE of the following: <ol style="list-style-type: none"> <li>1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member <b>OR</b></li> <li>2. BOTH of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer <b>OR</b></li> <li>2. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] <b>AND</b></li> </ol> </li> <li>B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration <b>OR</b></li> </ol> </li> </ol> </li> </ol> </li> </ol> </li> </ol> </li></ol>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] <b>OR</b></li> <li>4. The patient has tried and had an inadequate response to at least ONE of the following conventional agents [chart notes required]: <ol style="list-style-type: none"> <li>A. Mifepristone <b>OR</b></li> <li>B. Signifor/Signifor LAR (pasireotide) <b>OR</b></li> <li>C. Isturisa (osilodrostat) <b>OR</b></li> <li>D. Cabergoline <b>OR</b></li> <li>E. Metyrapone <b>OR</b></li> <li>F. Lysodren (mitotane) <b>OR</b></li> </ol> </li> <li>5. The patient discontinued mifepristone, pasireotide, osilodrostat, cabergoline, metyrapone, or mitotane due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>6. The patient has an intolerance or hypersensitivity to mifepristone, pasireotide, or osilodrostat [chart notes required] <b>OR</b></li> <li>7. The patient has an FDA labeled contraindication to mifepristone, pasireotide, AND osilodrostat [chart notes required] <b>OR</b></li> <li>8. Mifepristone, pasireotide, or osilodrostat is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; <b>OR</b> cause a significant barrier to the patient's adherence of care; <b>OR</b> worsen a comorbid condition; <b>OR</b> decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; <b>OR</b> cause an adverse reaction or cause physical or mental harm [chart notes required] <b>OR</b></li> <li>9. Mifepristone, pasireotide, or osilodrostat is not in the best interest of the patient based on medical necessity [chart notes required] <b>OR</b></li> <li>10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as mifepristone, pasireotide, osilodrostat, cabergoline, metyrapone, or mitotane and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>AND</b></li> </ol> <p>C. ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member <b>OR</b></li> <li>2. BOTH of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer <b>OR</b></li> <li>2. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] <b>AND</b></li> </ol> </li> <li>B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed,</li> </ol> </li> </ol>

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	<p style="text-align: center;">evidence-based literature; and approved by the United States Food and Drug Administration <b>OR</b></p> <ol style="list-style-type: none"> <li>3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] <b>OR</b></li> <li>4. The patient has tried and had an inadequate response to ketoconazole tablets [chart notes required] <b>OR</b></li> <li>5. Ketoconazole tablets were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>6. The patient has an intolerance or hypersensitivity to ketoconazole tablets that is NOT expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>7. The patient has an FDA labeled contraindication to ketoconazole tablets that is NOT expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>8. Ketoconazole tablets are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; <b>OR</b> cause a significant barrier to the patient’s adherence of care; <b>OR</b> worsen a comorbid condition; <b>OR</b> decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; <b>OR</b> cause an adverse reaction or cause physical or mental harm [chart notes required] <b>OR</b></li> <li>9. Ketoconazole tablets are not in the best interest of the patient based on medical necessity [chart notes required] <b>OR</b></li> <li>10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ketoconazole tablets and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b> <ol style="list-style-type: none"> <li>2. The patient has another FDA labeled indication for the requested agent and route of administration <b>AND</b></li> </ol> </li> </ol> <p>B. If the patient has an FDA labeled indication, then ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient’s age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>2. There is support for using the requested agent for the patient’s age for the requested indication <b>AND</b></li> </ol> <ol style="list-style-type: none"> <li>2. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li> <li>3. The patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy for the requested indication <b>AND</b></li> <li>4. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>All Other Plans: 6 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

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	<p><b>The requested agent will also be approved when ONE of the following is met:</b></p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> <li>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>B. The requested indication is a rare disease <b>AND</b></li> <li>C. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> </ol> </li> </ol> </li> <li>2. ALL of the following: <ol style="list-style-type: none"> <li>A. The member resides in Ohio <b>AND</b></li> <li>B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></li> <li>C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>D. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</li> </ol> </li> </ol> </li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: Patients not previously approved for the requested agent will require initial evaluation review) <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>4. The patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy for the requested indication <b>AND</b></li> </ol>

Module	Clinical Criteria for Approval
	<p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

### QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity Limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSIL: 12 months</p> <p>ALL other plans: INITIAL: 6 months, RENEWAL: 12 months</p>