



Korlym Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Korlym	mifepristone tab	300 MG	M ; N ; O ; Y	O ; Y		

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
Korlym	Mifepristone Tab 300 MG	300 MG	120	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Korlym	mifepristone tab	300 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
Korlym	Mifepristone Tab 300 MG	300 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>Initial Evaluation</p> <p>Target Agent will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of Cushing’s syndrome AND BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has type 2 diabetes mellitus OR 2. The patient has glucose intolerance as defined by a 2-hr glucose tolerance test plasma glucose value of 140-199 mg/dL AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has had an inadequate response to surgical resection OR 2. The patient is NOT a candidate for surgical resection OR 2. The patient has another FDA labeled indication for the requested agent and route of administration AND B. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> 1. The patient’s age is within FDA labeling for the requested indication for the requested agent OR 2. There is support for using the requested agent for the patient’s age for the requested indication AND 2. If the request is for ONE of the following brand agents with an available generic equivalent, then ONE of the following: <table border="1" style="width: 100%; margin-top: 10px;"> <thead> <tr> <th>Brand</th> <th>Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td>Korlym</td> <td>mifepristone</td> </tr> </tbody> </table> <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 	Brand	Generic Equivalent	Korlym	mifepristone
Brand	Generic Equivalent				
Korlym	mifepristone				

Module	Clinical Criteria for Approval
	<p>B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>C. The patient has tried and had an inadequate response to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes required] OR</p> <p>D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>E. The patient has an intolerance or hypersensitivity to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes required] OR</p> <p>F. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes required] OR</p> <p>G. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>H. The generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>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 AND</p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>5. The requested dose does NOT exceed 20 mg/kg/day</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSNM: 12 months</p> <p>All other plans: 6 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <p>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <ul style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR <p>2. ALL of the following:</p> <ul style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND

Module	Clinical Criteria for Approval				
	<p>C. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>D. ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 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] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: 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>Length of Approval:</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>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 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) AND 2. The patient has had clinical benefit with the requested agent AND 3. If the request is for ONE of the following brand agents with an available generic equivalent, then ONE of the following: <table border="1" data-bbox="235 1514 1227 1591"> <thead> <tr> <th data-bbox="235 1514 732 1549">Brand</th> <th data-bbox="732 1514 1227 1549">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 1549 732 1591">Korlym</td> <td data-bbox="732 1549 1227 1591">mifepristone</td> </tr> </tbody> </table> <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR C. The patient has tried and had an inadequate response to the generic equivalent that is NOT expected to occur with the requested brand agent [chart notes required] OR D. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR E. The patient has an intolerance or hypersensitivity to the generic equivalent that is NOT expected to occur with the requested agent [chart notes required] OR 	Brand	Generic Equivalent	Korlym	mifepristone
Brand	Generic Equivalent				
Korlym	mifepristone				

Module	Clinical Criteria for Approval
	<p>F. The patient has an FDA labeled contraindication to the generic equivalent that is NOT expected to occur with the requested agent [chart notes required] OR</p> <p>G. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>H. The generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>J. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>4. 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 AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>6. The requested dose does NOT exceed 20 mg/kg/day</p> <p>Length of Approval:</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>Quantity limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 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 <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans - Initial: 6 months; Renewal: 12 months</p>

