BlueCross BlueShield of Illinois
BlueCross BlueShield of Montana
BlueCross BlueShield of New Mexico
BlueCross BlueShield of Oklahoma
BlueCross BlueShield of Texas

Korlym Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
01-01-2025

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 Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; 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 Annual 2025 ; HIM Quarterly 2024

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM Performance ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 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: A. BOTH of the following: 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: 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 **Length of Approval:** Initial: 6 months; Renewal: 12 months

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent** will be approved when ALL of the following are met: 1. The patient has a diagnosis of Cushing's syndrome **AND** A. If the patient has an FDA labeled indication, then ONE of the following: 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** B. ONE of the following: 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** C. ONE of the following: 1. The patient has had an inadequate response to surgical resection **OR** 2. The patient is NOT a candidate for surgical resection **AND** 2. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following: **Brand** / **Generic Equivalent** Korlym / mifepristone

Module	Clinical Criteria for Approval
	A. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] **OR** B. The patient has tried and had an inadequate response to the generic equivalent that is NOT expected to occur with the brand agent [chart notes are required] **OR** C. An available generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] **OR** D. The patient has an intolerance or hypersensitivity to an available generic equivalent that is NOT expected to occur with the requested agent [chart notes are required] **OR** E. The patient has an FDA labeled contraindication to an available generic equivalent that is NOT expected to occur with the requested agent [chart notes are required] **OR** F. An available 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 are required] **OR** G. An available generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes are required] **OR** H. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as an available generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] **AND** 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** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested dose does NOT exceed 20 mg/kg/day **Length of Approval:** BCBSIL: 12 months All other plans: 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **The requested agent will also be approved when the following are met:** 1. The member resides in Ohio **AND** 2. The plan is Fully Insured or HIM Shop (SG) **AND** BOTH of the following A. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** B. ONE of the following: 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

Module	Clinical Criteria for Approval
	blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] **Non-oncology compendia allowed:** DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive) **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 **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 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 (listed below), then ONE of the following: **Brand** / **Generic Equivalent** Korlym / mifepristone A. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] **OR** B. The patient has tried and had an inadequate response to the generic equivalent that is NOT expected to occur with the brand agent [chart notes are required] **OR** C. An available generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] **OR** D. The patient has an intolerance or hypersensitivity to an available generic equivalent that is NOT expected to occur with the requested agent [chart notes are required] **OR** E. The patient has an FDA labeled contraindication to an available generic equivalent that is NOT expected to occur with the requested agent [chart notes are required] **OR** F. An available 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 are required] **OR** G. An available generic equivalent is NOT in the best interest of the patient based on medical necessity [chart notes are required] **OR** H. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as an available generic equivalent and that prescription drug was discontinued due to lack of efficacy

Module	Clinical Criteria for Approval
	or effectiveness, diminished effect, or an adverse event [chart notes are required] **AND** 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** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The requested dose does NOT exceed 20 mg/kg/day **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.