

Pharmacy Policy Bulletin

Title: Mifepristone (Korlym®)

Policy #: Rx.01.121

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for **mifepristone (Korlym®)** as provided under the member's prescription drug benefit.

▶ **Description:**

Korlym® (mifepristone) is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

Mifepristone blocks the glucocorticoid receptor (GR-II) at higher doses. Mifepristone has high affinity for the GR-II receptor but little affinity for the GR-I (MR, mineralocorticoid) receptor. Mifepristone also exhibits weak antiandrogenic activity. In addition, mifepristone appears to have little or no affinity for estrogen, muscarinic, histaminic, or monoamine receptors.

▶ **Policy:**

Mifepristone (Korlym®) is approved when documentation is provided of ALL of the following:

1. Hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance; and
2. Member has failed surgery or is not a candidate for surgery; and
3. Prescribed by or in consultation with an endocrinologist

▶ **Black Box Warning:**

Termination of pregnancy: Mifepristone is a potent antagonist of progesterone and cortisol via the progesterone and glucocorticoid (GR-II) receptors, respectively. The antiprogesterational effects will result in the termination of pregnancy.

Pregnancy must be excluded before the initiation of treatment with mifepristone and prevented during treatment and for 1 month after stopping treatment by the use of a nonhormonal, medically acceptable method of contraception unless the patient has had a surgical sterilization, in which case, no additional contraception is needed. Pregnancy must also be excluded if treatment is interrupted for more than 14 days in females of reproductive potential.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Korlym® (mifepristone) [package insert]. Menlo Park, CA. Corcept Therapeutics Incorporated. May 2017. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202107s000lbl.pdf. Accessed November 12, 2018.

Micromedex website [Korlym]. Available at www.micromedex.com. Accessed November 26, 2018.

Applicable Drugs:

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Name	Generic Name
Korlym®	Mifepristone

Cross References:

N/A

Policy Version Number:	7.00
P&T Approval Date:	October 11, 2018
Policy Effective Date:	January 1, 2019
Next Required Review Date:	October 11, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.