# Clinical Policy: Mifepristone (Korlym)

Reference Number: ERX.SPA.15
Effective Date: 07.01.16
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Mifepristone (Korlym®) is a cortisol receptor blocker.

**FDA Approved Indication(s)**
Korlym 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.

Limitation(s) of use: Do not use for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Korlym is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Cushing's Syndrome** (must meet all)**:**

1. Diagnosis of uncontrolled hyperglycemia secondary to endogenous Cushing's syndrome;
2. Member has type 2 diabetes mellitus, impaired glucose tolerance or pre-diabetes as evidenced by a fasting blood glucose, oral glucose tolerance test, or hemoglobin A1c;
3. Prescribed by or in consultation with an endocrinologist;
4. Age ≥ 18 years;
5. Surgery to treat Cushing's syndrome was insufficient, or member is not a candidate for surgery;
6. At the time of request, member does not have any of the following contraindications (a and b):
   a. Concurrent use of drugs metabolized by CYP3A (e.g., simvastatin, lovastatin) or CYP3A substrates with narrow therapeutic ranges (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus);
   b. Concurrent long-term corticosteroid use;
7. Dose does not exceed 1,200 mg (4 tablets) per day.

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## II. Continued Therapy

**A. Cushing's Syndrome** (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: improved fasting blood glucose, oral glucose tolerance test, or hemoglobin A1c since initiation of therapy;
3. If request is for a dose increase, new dose does not exceed 1,200 mg (4 tablets) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Pregnancy
  - Concurrent use of drugs metabolized by CYP3A (e.g., simvastatin, lovastatin) or CYP3A substrates with narrow therapeutic ranges (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus)
  - Concurrent systemic corticosteroids for lifesaving purposes (e.g., immunosuppression after organ transplantation)
  - Women with history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma
  - Known hypersensitivity to mifepristone
- Boxed warning(s): termination of pregnancy

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Cushing's syndrome | Starting dose is 300 mg PO QD. May increase in 300 mg increments (dose increase once every 2 to 4 weeks). | 1,200 mg/day |

## VI. Product Availability

Tablet: 300 mg

## VII. References

1. Korlym Prescribing Information. Menlo Park, CA: Corcept Therapeutics, Inc.; November 2019. Available at www.korlym.com. Accessed September 22, 2021.
2. Nieman LK, Biller BMK, Findling JW et al. Treatment of Cushing's syndrome: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2015; 100(8): 2807-2831.

3. Fleseriu M, Molitch ME, Gross C, et al. A new therapeutic approach in the medical treatment of Cushing's syndrome: glucorticoid receptor blockade with mifepristone. *Endocr Pract*. March/April 2013; 19(2): 313-326.
4. American Diabetes Association. Standards of medical care in diabetes—2019. Diabetes Care. 2019; 42(suppl 1): S1-S193. Updated July 31, 2019. Accessed November 5, 2019.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 1Q18 annual review:<br>Age added. "Adherence to an anti-diabetic regimen" is removed due to verification challenge. "Dose does not exceed 1200 mg/day or 20 mg/kg per day, whichever is less" is edited to "Dose does not exceed 1200 mg/day". References updated. | 11.17.17 | 02.18 |
| 1Q 2019 annual review: no significant changes; pregnancy removed as a contraindication; references reviewed and updated. | 11.13.18 | 02.19 |
| 1Q 2020 annual review: no significant changes; references reviewed and updated. | 11.05.19 | 02.20 |
| 1Q 2021 annual review: no significant changes; references reviewed and updated. | 11.03.20 | 02.21 |
| 1Q 2022 annual review: no significant changes; clarified diagnosis requirement by separating into two separate requirements; references reviewed and updated. | 09.22.21 | 02.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.