Generic Name: mifepristone

Therapeutic Class or Brand Name: Korlym®

Applicable Drugs: Korlym®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/20/2025

Date Last Reviewed / Revised: 1/20/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of endogenous Cushing's syndrome AND must meet all criteria listed:
   A. Documented diagnosis of type 2 diabetes mellitus or glucose intolerance.
      i. Diagnosed by fasting plasma glucose, oral glucose tolerance test, or hemoglobin A1c.
   B. Documentation that hyperglycemia is secondary to hypercortisolism.
   C. Documented failure of previous pituitary resection surgery, or documentation of reason(s) that patient is not a candidate for pituitary surgery.
   D. Documented clinically significant treatment failure to one, or contraindication to all, of the following treatments for the treatment of endogenous Cushing's syndrome: ketoconazole, metyrapone, mitotane, pasireotide.
   E. For females of reproductive potential:
      i. Documentation of negative pregnancy test prior to initiation of Korlym and/or if treatment is interrupted for more than 14 days.
      ii. Documentation of the contraceptive method or regimen that will be used during treatment with mifepristone must be provided.
   F. Requested dose does not exceed 1200 mg per day or 20mg/kg per day, whichever is less.
   G. Adherence to an anti-diabetic regimen that includes lifestyle modifications.
   H. Age 18 years of age or older.

II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

III. Drug is prescribed by or in consultation with an endocrinologist.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

Exclusion Criteria

- Pregnancy
- Patients taking drugs metabolized by CYP3A such as simvastatin, lovastatin, cyclosporine, or tacrolimus, and/or taking CYP3A substrates with narrow therapeutic ranges.
- Patients receiving systemic corticosteroids for lifesaving purposes.
- Women with a history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma.
- Severe hepatic impairment (such as Child-Pugh Class C).
- Use for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- For patients without the below factors affecting Korlym dosing:
  - 120 tablets per 30 days.
- For patients concomitantly receiving strong CYP3A inhibitors:
  - 90 tablets per 30 days.
- For patients with mild-to-moderate hepatic impairment (Child-Pugh Class B) or severe renal impairment (CrCl < 30 mL/min):
  - 60 tablets per 30 days.

Approval Length

- **Authorization:** 12 months
- **Re-Authorization:** 12 months, with evidence of improved glycemic control as demonstrated by improvement in fasting plasma glucose, oral glucose tolerance test, or hemoglobin A1c.

Appendix

N/A

References

1. Korlym. Prescribing information. Corcept Therapeutics; 2019. Accessed December 13, 2024. https://www.korlym.com/pdfs/KorlymPrescribingInformation.pdf

2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818
3. Brown DR, East HE, Eilerman BS, et al. Clinical management of patients with Cushing syndrome treated with mifepristone: consensus recommendations. *Clin Diabetes Endocrinol*. 2020;6(1):18. doi:10.1186/s40842-020-00105-4
4. Kahn SE, et al. "American Diabetic Association (ADA): Standards of Care in Diabetes - 2025." Diabetes Care. 2025 Jan 1;48(Supplement_1):S27-S49. doi: 10.2337/dc25-S002