

Applicable Drugs: Korlym (mifepristone)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/20/2025

Date Last Reviewed / Revised: 1/27/2026

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 hemoglobin A1c, fasting plasma glucose, or oral glucose tolerance test.
 - B. Documentation that hyperglycemia is secondary to hypercortisolism.
 - C. Documented failure of previous pituitary resection surgery, or documented 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 that will be used during treatment with mifepristone.
 - F. The requested dose does not exceed 1200 mg per day or 20mg/kg per day, whichever is less.
 - G. Documented 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

- Standard 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 ($\text{CrCl} < 30 \text{ mL/min}$):
 - 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 hemoglobin A1c, fasting plasma glucose, or oral glucose tolerance test.

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

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.