Pharmacy Policy Bulletin: J-0155 Korlym (mifepristone) – Commercial and Healthcare Reform	
Number: J-0155	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1.):** **Prior Authorization** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform**: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0155-015	**Original Date:** 06/06/2012
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Korlym (mifepristone)
FDA-Approved Indication(s):	• 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.

Background:	• Korlym (mifepristone) is a selective antagonist of the progesterone receptor at low doses and blocks the glucocorticoid receptor (GR-II) at higher doses. Korlym has high affinity for the GR-II receptor but little affinity for the GR-I (mineralocorticoid) receptor.
	• The Endocrine Society guidelines for the treatment of Cushing's syndrome recommend complete surgical resection of the primary lesion(s) underlying Cushing's disease, unless surgery is not possible or unlikely to significantly reduce glucocorticoid excess. For patients who underwent a non-curative surgery or for whom surgery was not possible, second-line treatment options include additional surgeries, radiotherapy, and pharmacological therapy.
	• Treating diabetes in patients with Cushing's syndrome does not essentially differ from treating it in ordinary circumstances. Metformin remains the first-line therapy of hyperglycemia in Cushing's syndrome. Other antidiabetic drugs recommended include sulfonylureas, dipeptidyl peptidase-4 inhibitors, and insulin.
	• Prescribing Considerations:
	  ○ Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.
	  ○ Korlym results in the termination of pregnancy. A negative pregnancy test in females of reproductive potential should be obtained prior to initiating treatment with Korlym or if treatment is interrupted for more than 14 days.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Korlym may be approved when all of the following criteria are met **(A. through D.)**:

- **A.** The member is 18 years of age or older.
- **B.** The member has a diagnosis of endogenous Cushing's syndrome (ICD-10: E24).
- **C.** The member meets one (1) the following criteria **(1. or 2.)**:
  - **1.** The member is not a candidate for surgery.
  - **2.** The member has experienced therapeutic failure to surgery.
- **D.** The member meets one (1) of the following criteria **(1. or 2.)**:
  - **1.** The member has a diagnosis of type 2 diabetes mellitus (ICD-10: E11) and one (1) of the following criteria is met **(a. or b.)**:
    - **a.** The member has experienced therapeutic failure to one (1) previous pharmacologic therapy for type 2 diabetes.
    - **b.** The member is taking Korlym in addition to pharmacologic therapy for type 2 diabetes.
  - **2.** The member has glucose intolerance.

II. Reauthorization

When a benefit, reauthorization of Korlym may be approved when the following criterion is met **(A.)**:

- **A.** The prescriber provides documentation that the member has experienced improvement in hyperglycemia following Korlym administration.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Korlym should not be used in members who are pregnant.

II. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or Healthcare Reform members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics; November 2019.
2. Barbot M, Ceccato F, Scaroni C. Diabetes Mellitus Secondary to Cushing's Disease. *Front. Endocrinol*. 2018;9:284.
3. Fleseriu M, Biller BM, Finding JW, et al. Mifepristone, a glucocorticoid receptor antagonist, produces clinical and metabolic benefits in patients with Cushing's syndrome. *J Clin Endocrinol Metab*. 2012;97(6):2039.
4. Castinetti, Fassnacht M, Johanssen S, et al. Merits and pitfalls of mifepristone in Cushing's syndrome. *Eur J Endocrinol*. 2009; 160(6):1003-10.
5. Lynnette K. et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8)2807-2831.