Commercial/Healthcare Exchange PA Criteria

Effective: April 27,2020

Prior Authorization: Korlym

Products Affected: Korlym (mifepristone) Oral Tablet

Medication Description:

Korlym (mifepristone) is a cortisol receptor blocker 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.

Korlym carries a black box warning because mifepristone is a potent antagonist of progesterone and cortisol via the progesterone and glucocorticoid (GR-II) receptors, respectively. The antiprogestational effects will result in the termination of pregnancy. Pregnancy must therefore be excluded before the initiation of treatment with Korlym and prevented during treatment and for one month after stopping treatment by the use of a non-hormonal 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.

Covered Uses: Hyperglycemia - Endogenous Cushing's syndrome

Exclusion Criteria:

1. Pregnancy
2. Concurrent use with simvastatin, lovastatin, and CYP3A substrates with narrow therapeutic ranges, such as cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus
3. Concurrent long-term corticosteroid use
4. Women with history or unexplained vaginal bleeding
5. Women with endometrial hyperplasia with atypia or endometrial carcinoma

Required Medical Information:

1. Documentation of diagnosis of endogenous Cushing’s syndrome
2. Documentation of diagnosis of type 2 diabetes mellitus or glucose intolerance
3. Documentation of surgical history, hemoglobin A1c, and plasma glucose levels

Age Restrictions: ≥ 18 years of age

Prescriber Restrictions: Prescribed by or in consultation with an endocrinologist.

Coverage Duration: 12 months

Other Criteria:

Approve Korlym if the patient meets the following criteria (A, B, **and** C):

A. Patient has a clinically confirmed diagnosis of endogenous Cushing’s syndrome; **AND**
B. One of the following:
    a. Patient has diagnosis of type 2 diabetes mellitus; **OR**

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b. Patient has diagnosis of glucose intolerance; **AND**

C. Surgery is not an option **OR** has not been curative for the patient

References:

1. Korlym [Package Insert]. Menlo Park, CA: Corcept Therapeutics, Inc.; March 2014.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/13/2016
2	Policy Update	Added Exclusion criteria to match FDA Label	All	10/15/2019
	Policy Update	CCI adopted EH policy Removal from	Reviewed covered uses and exclusion criteria to FDA label	4/27/2020

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