Korlym

Description

Korlym (mifepristone)

Background
Korlym (mifepristone) is a potent antagonist of progesterone and cortisol via progesterone and glucocorticoid (GR-II) receptor respectively, which affects the hypothalamic-pituitary-adrenal (HPA) axis to further increase circulating cortisol levels while, at the same time, blocking their effects. Korlym does not decrease cortisol production but reduces the effects of excess cortisol (e.g. hyperglycemia). The antiprogestational effects will result in the termination of pregnancy. It has been approved 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 (1).

Regulatory Status
FDA-approved indication: Korlym 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 (1).

Limitations of Use:
Korlym cannot be used in the treatment of patients with type 2 diabetes mellitus unrelated to endogenous Cushing’s syndrome (1).

Korlym carries a boxed warning regarding termination of pregnancy resulting from the antiprogestational effects of the drug. Korlym is a pregnancy category X. Pregnancy must be
excluded before the initiation of treatment with Korlym, or if treatment is interrupted for more than 14 days in females of reproductive potential (1).

The use of Korlym in women with a history of unexplained vaginal bleeding and endometrial hyperplasia with atypia or endometrial carcinoma is also contraindicated (1).

Korlym should be used with caution in patients with certain conditions including adrenal insufficiency, hyopkalemia, vaginal bleeding, and QT prolongation. Dosage should not exceed 600mg a day in patients with renal impairment or mild to moderate hepatic impairment. Korlym should not be used in patients with severe hepatic impairment (1).

The use of Korlym to terminate pregnancy is not a covered benefit.

Safety and effectiveness have not been established in pediatric patients (1).

### Related policies

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Korlym may be considered **medically necessary** in patients 18 years and older with endogenous Cushing's syndrome and if the conditions indicated below are met.

Korlym is considered **investigational** in patients less than 18 years of age and for all other indications.

The use of Korlym to terminate pregnancy is not a covered benefit.

### Prior-Approval Requirements

**Age**  
18 years of age and older

**Diagnosis**

Patient must have **ALL** of the following:

1. Endogenous Cushing’s syndrome
2. Type 2 diabetes mellitus or glucose intolerance
3. Have failed surgery or are not a candidate for surgery
4. Females of childbearing potential should have pregnancy excluded before the initiation of treatment
5. NO severe hepatic impairment

Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration  12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Korlym (mifepristone) is a potent antagonist of progesterone and cortisol. It 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. Korlym carries a boxed warning regarding termination of pregnancy and carries a pregnancy category X. The use of Korlym in women with a history of unexplained vaginal bleeding and endometrial hyperplasia with atypia or endometrial carcinoma is also contraindicated. Korlym should be used with caution in patients with certain conditions including adrenal insufficiency, hypokalemia, vaginal bleeding, and QT prolongation. Safety and effectiveness have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Korlym while maintaining optimal therapeutic outcomes.

References
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Endocrine and Metabolic Drugs  Original Policy Date: August 15, 2012
Subject: Korlym  Page: 4 of 4

Policy History

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<tr>
<td>September 2012</td>
<td>New Policy</td>
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<tr>
<td>March 2013</td>
<td>Look alike/sound alike precaution of mifepristone – misoprostol</td>
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<tr>
<td>June 2013</td>
<td>Annual editorial review and reference update</td>
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<td>Addition to criteria that females of reproductive potential should not be pregnant due to the boxed warning of pregnancy loss.</td>
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<td>September 2014</td>
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<td>September 2016</td>
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<td></td>
<td>Policy number changed from 5.08.25 to 5.30.25</td>
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<tr>
<td>December 2017</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.