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5.30.025

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	August 15, 2012
Subject:	Korlym	**Page:**	1 of 4

Last Review Date: September 6, 2024

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. 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).

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

Related policies
Isturisa, Signifor, Signifor LAR

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** if the conditions indicated below are met.

Korlym may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Endogenous Cushing's syndrome

AND ALL of the following:

1. Type 2 diabetes mellitus or glucose intolerance
2. Patient has failed surgery, or patient is not a candidate for surgery

3. Females of childbearing potential **only**: prescriber agrees that pregnancy will be excluded before the initiation of treatment
4. **NO** severe hepatic impairment (Child-Pugh Class C)

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Endogenous Cushing's syndrome

AND ALL of the following:

1. Type 2 diabetes mellitus or glucose intolerance
2. **NO** severe hepatic impairment (Child-Pugh Class C)

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. 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

1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics Inc.; November 2019.

Policy History

Date	Action
September 2012	New Policy
March 2013	Look alike/sound alike precaution of mifepristone –misoprostol
June 2013	Annual editorial review and reference update Addition to criteria that females of reproductive potential should not be pregnant due to the boxed warning of pregnancy loss.
September 2014	Annual editorial review and reference update
September 2015	Annual editorial review
September 2016	Annual editorial review and reference update Policy number changed from 5.08.25 to 5.30.25
December 2017	Annual editorial review and reference update
November 2018	Annual review
December 2019	Annual review
September 2020	Annual review and reference update
June 2021	Annual review
June 2022	Annual editorial review. Revised requirements for clarity and removed pituitary surgery and pregnancy exclusion requirements from continuation
June 2023	Annual review. Changed policy number to 5.30.025
June 2024	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.