Clinical Policy: Mifepristone (Korlym)

Reference Number: PA.CP.PHAR.101
Effective Date: 01/18
Last Review Date: 04/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for mifepristone (Korlym®).

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Korlym is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cushing's Syndrome (must meet all):

1. Prescribed by or in consultation with an endocrinologist;
2. Diagnosis of endogenous Cushing's syndrome and all of the following:
   a. Current uncontrolled hyperglycemia (diagnosed as type 2 diabetes or impaired glucose tolerance/pre-diabetes by fasting plasma glucose, an oral glucose tolerance test, or hemoglobin A1c);
   b. The hyperglycemia is secondary to hypercortisolism;
   c. Surgery to treat Cushing's syndrome was insufficient or member is not a candidate for surgery;
   d. Adherence to an anti-diabetic regimen;
3. Prescribed dose of Korlym does not exceed 1200 mg/day or 20 mg/kg per day, whichever is less;
4. At the time of request, member does not have any of the following contraindications:
   a. Pregnancy;
   b. Concurrent use of simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges (example: cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, or tacrolimus);
   c. Concurrent long term corticosteroid use;
   d. History of unexplained vaginal bleeding;
   e. Endometrial hyperplasia with atypia or endometrial carcinoma;

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Cushing's Syndrome (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Evidence of improved glycemic control by fasting plasma glucose, an oral glucose tolerance test, or hemoglobin A1c.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Korlym (mifepristone), a cortisol receptor blocker for oral administration, acts as a selective antagonist of the progesterone receptor at low doses and blocks the glucocorticoid receptor (GR-II) at higher doses. Mifepristone has high affinity for the GR-II receptor but little affinity for the GR-I (MR, mineralocorticoid) receptor. In addition, mifepristone appears to have little or no affinity for estrogen, muscarinic, histaminic, or monoamine receptors.

Formulations:
Tablets: 300mg

FDA Approved Indication:

Korlym (mifepristone) is a cortisol receptor blocker/oral tablet 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.

Limitations of use:

- Do not use for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
S0190	Mifepristone, oral, 200 mg

Reviews, Revisions, and Approvals	Date	Approval Date

References

1. Korlym Prescribing Information. Menlo Park, CA: Corcept Therapeutics, Inc.; October 2016. Available at www.korlym.com. Accessed March 17, 2017.

2. Nieman LK, Biller BMK, Findling JW et al. Treatment of Cushing's syndrome: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100(8): 2807-2831.
3. Standards of medical care in diabetes – 2013: position statement. American Diabetes Association. Diabetes Care 2013; 36(Suppl 1): S11-S66.
4. Fleseriu M, Molitch ME, Gross C, et al. A new therapeutic approach in the medical treatment of Cushing's syndrome: glucorticoid receptor blockade with mifepristone. Endocr Pract. March/April 2013; 19(2): 313-326.