Clinical Policy: Mifepristone (Korlym)
Reference Number: PA.CP.PHAR.101
Effective Date: 01/18
Last Review Date: 07/18

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®).

FDA Approved Indication(s)
Korlym 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.

Limitation(s) of use: Do not use for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

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. Diagnosis of the following (a and b):
      a. Uncontrolled hyperglycemia secondary to endogenous Cushing’s syndrome;
      b. Type 2 diabetes mellitus, impaired glucose tolerance or pre-diabetes as evidenced by a fasting blood glucose, oral glucose tolerance test, or hemoglobin A1c;
   2. Prescribed by or in consultation with an endocrinologist;
   3. Age ≥ 18 years;
   4. Surgery to treat Cushing’s syndrome was insufficient or member is not a candidate for surgery;
   5. 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 (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus);
      c. Concurrent long-term corticosteroid use;
   6. Dose does not exceed 1200 mg/day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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.
3. If request is for a dose increase, new dose does not exceed 1200 mg/day.

**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; **Approval duration: Duration of request 6 months** (whichever is less); or

   2. Refer to PA.CP.PMN.53

**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

**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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>S0190</td>
<td>Mifepristone, oral, 200 mg</td>
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<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>-Age added. “Adherence to an anti-diabetic regimen” is removed due to verification challenge. The following contraindications are removed due to verification challenge: history of unexplained vaginal bleeding; endometrial hyperplasia with atypia or endometrial carcinoma. “Dose does not exceed 1200 mg/day or 20 mg/kg per day, whichever is less” is edited to “Dose does not exceed 1200 mg/day”. References reviewed and updated.</td>
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References