OVERVIEW

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. Korlym should not be used for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing’s syndrome. Mifepristone is also available as Mifeprex [mifepristone 200 mg tablets] indicated for the medical termination of intrauterine pregnancy through 70 days’ pregnancy. Mifeprex is not included in this prior authorization policy.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Korlym. All approvals are provided for 1 year in duration unless otherwise noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Korlym is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Endogenous Cushing’s Syndrome.** Approve in patients who meet the following criteria (a, b, c, and d):
   a) Patient is $\geq$ 18 years of age; AND
   b) Korlym is prescribed by or in consultation with an endocrinologist; AND
   c) According to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative; AND
   d) The patient has tried ketoconazole tablets, Metopirone (metyrapone capsules), Lysodren (mitotane tablets), or Signifor for the treatment of Cushing’s syndrome.

Other Uses with Supportive Evidence

1. **Endogenous Cushing’s Syndrome, Patients Awaiting Surgery.** Approve for 2 months if the patient meets the following criteria (a and b):
   a) Patient is $\geq$ 18 years of age; AND
   b) Korlym is prescribed by or in consultation with an endocrinologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Korlym has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.
Rationale for non-coverage for these specific conditions are provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Exogenous (Iatrogenic) Cushing’s Syndrome.** Korlym is not indicated in exogenous Cushing’s syndrome. Exogenous Cushing’s syndrome is caused by excessive glucocorticoid administration. Therefore, the process to reverse the excessive cortisol exposure is to taper or discontinue the offending drug when possible.

2. **Type 2 Diabetes Not Associated with Endogenous Cushing’s Syndrome.** Korlym should not be used for the treatment of type 2 diabetes unrelated to endogenous Cushing’s syndrome.

3. **Psychotic Features of Psychotic Depression.** The manufacturer is conducting Phase III studies with mifepristone to treat the psychotic features of psychotic depression. Mifepristone is being investigated as an alternative to electroconvulsive therapy (ECT) or combination drug therapy to determine whether patients with psychotic features of psychotic depression who are treated with mifepristone can be more easily maintained on antidepressant therapy alone without the need for ECT or antipsychotic medication. Individual trials have demonstrated variable efficacy results. In some of the studies comparing mifepristone with placebo, various statistically significant improvements in psychiatric symptoms have been noted with mifepristone relative to placebo; however, the methodology and statistical analyses of some studies have been questioned. Data are inconclusive.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**