Korlym® (mifepristone)
Approved April 2021

Background:
KORLYM (mifepristone) 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 (T2D) or glucose intolerance and have failed surgery or are not candidates for surgery.

Criteria for approval:

1. Patient has a diagnosis of Cushing's syndrome with one of the following:
   a. Type 2 diabetes mellitus OR
   b. Diagnosis of glucose intolerance
   And ONE of the following:
   a. Patient has failed surgical resection OR
   b. Patient is not a candidate for surgery
2. Medication is prescribed by or in consultation with an endocrinologist
3. Patient does not have any contraindication(s) to therapy such as:
   a. Pregnancy
   b. Patients taking drugs metabolized by CYP3A such as simvastatin, lovastatin, and CYP3A substrates with narrow therapeutic ranges, such as cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus
   c. Patients receiving systemic corticosteroids for lifesaving purposes (for example, immunosuppression after organ transplantation)
   d. Patients with a history of unexplained vaginal bleeding or with endometrial hyperplasia with atypia or endometrial carcinoma
4. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
5. Weight must be received for drugs that have weight-based dosing.

Initial Approval Duration: 6 months

Quantity Level Limit: 1200mg per day

Continuation of therapy:

1. The patient has shown improvement or stabilization of glucose control in fasting serum glucose test, oral glucose tolerance test or hemoglobin A1c test.
2. For dose increase requests, weight must be received for drugs that have weight-based dosing
3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital

Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Renewal Approval Duration: 12 months

Quantity Level Limit: 1200mg per day

References:

1. Korlym [package insert]. Corcept Therapeutics, Inc. Menlo Park, CA, November 2019
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Nieman LK, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, 2015;100: 2807-2831
4. Nieman LK. Recent Updates on the Diagnosis and Management of Cushing's Syndrome. Endocrinol Metab (Seoul). 2018 Jun; 33(2): 139–146.
5. Fleseriu M, et al. Mifepristone, a Glucocorticoid Receptor Antagonist, Produces Clinical and Metabolic Benefits in Patients with Cushing's Syndrome. J Clin Endocrinol Metab. 2012;97(6):2039-2049.