Korlym (mifepristone)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial Requests: 6 months Maintenance Therapy Requests: 12 months

Medications	Quantity Limit
Korlym (mifepristone)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Korlym (mifepristone) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Documentation is provided that individual has a diagnosis of endogenous Cushing's syndrome; **AND**
III. Individual has one of the following:
   A. Type 2 diabetes mellitus (T2DM), and documentation is provided; **OR**
   B. Impaired glucose tolerance (IGT), and documentation is provided;

AND
IV. Diagnosis of Cushing's has been verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: 24-hour urinary free cortisol (UFC) test; Dexamethasone suppression test (DST); Late-night salivary cortisol (LNSC) test) that are indicative of a positive test;

AND
V. One of the following:
   A. Individual is NOT a candidate for surgery that is expected to correct the cause of endogenous Cushing's syndrome; **OR**
   B. Disease persists or recurs following surgery intended to correct the cause of endogenous Cushing's syndrome.

Continuation of therapy requests for Korlym (mifepristone) may be approved if the following criteria are met:

I. Individual continues to meet the initial request approval criteria; **AND**
II. Documentation is provided that individual has experienced an improvement in or stabilization of glucose control as assessed by fasting serum glucose test, oral glucose tolerance test, or hemoglobin A1c test.

Requests for **brand** Korlym must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has failed an adequate trial of one chemically equivalent generic mifepristone agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**

A. Generic mifepristone had inadequate response; **OR**
B. Generic mifepristone caused adverse outcome; **OR**
C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Korlym (mifepristone) may not be approved for the following:

I. For the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome; **OR**
II. Individual has a history of unexplained vaginal bleeding; **OR**
III. Individual has current endometrial hyperplasia with atypia or endometrial carcinoma; **OR**
IV. Individual has a diagnosis of severe hepatic impairment (Child Pugh Class C); **OR**
V. Used in combination with any of the following:
   A. Long term systemic corticosteroids for serious medical conditions or illnesses; **OR**
   B. Simvastatin or lovastatin; **OR**
   C. CYP3A substrates with narrow therapeutic ranges (including but not limited to cyclosporine, fentanyl, sirolimus, tacrolimus); **OR**
   D. CYP3A inducers (including but not limited to, rifampin, phenobarbital, phenytoin, carbamazepine); **OR**
   E. Agents or co-morbid conditions which prolong the QT interval; **OR**
   F. Hormonal contraceptives.

Note:
Korlym (mifepristone) has a black box warning for the use in pregnancy. Prior to therapy initiation or if therapy interrupted for more than 14 days, pregnancy must be excluded in females of reproductive potential. Pregnancy should be prevented with a non-hormonal medically acceptable method of contraception during therapy. Women who have undergone surgical sterilization are exempt from the contraceptive requirement. Korlym is pregnancy category X.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Fleseriu M, Biller BMK, Findling JW, 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. Available from: http://press.endocrine.org/doi/pdf/10.1210/jc.2011-3350.
4. Katznelson L, Loriaux DL, Feldman D, et al. Global clinical response in Cushing's syndrome patients treated with mifepristone. *Clin Endocrinol (Oxf)*. 2014; 80:562-569. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4255292/pdf/cen0080-0562.pdf.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Nieman L, Biller B, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 100: 2807–2831, 2015. Available from: https://academic.oup.com/jcem/article/100/8/2807/2836065.