

Korlym (mifepristone)

| Override(s) | Approval Duration |
|---------------------|---|
| Prior Authorization | Initial Requests: 6 months |
| Quantity Limit | 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 confirmed 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.

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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 7, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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>. Accessed on: January 7, 2022.
5. 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>. Accessed on: July 12, 2022.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. 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>

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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