

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Korlym (mifepristone)

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

Medications	Quantity Limit
Korlym (mifepristone)	N/A

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. Individual has a diagnosis of endogenous Cushing's syndrome with one of the following:
 - A. Type 2 diabetes mellitus (T2DM); **OR**
 - B. Impaired glucose tolerance (IGT);

AND

- III. 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. 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. History of unexplained vaginal bleeding; **OR**
- II. Current endometrial hyperplasia with atypia or endometrial carcinoma; **OR**
- III. Diagnosis of severe hepatic impairment (Child Pugh Class C); **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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IV. Concomitant use 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 (such as but not limited to cyclosporine, fentanyl, sirolimus, tacrolimus); **OR**
- D. CYP3A inducers (such as but not limited to, rifampin, phenobarbital, phenytoin, carbamazepine); **OR**
- E. Agents or co-morbid conditions which prolong the QT interval.

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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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