

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Mifepristone (Korlym)

Notes:

- ^ Trans-sphenoidal surgery for pituitary dependent Cushing's or surgical removal of an adrenocortical tumor or a source of ectopic ACTH in malignant Cushing's.

Initiation (new start) criteria: Non-formulary **mifepristone (Korlym)** will be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Patient is at least 18 years of age
- Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)
- Diagnosis of type 2 diabetes mellitus **-OR-** patient has glucose intolerance (defined as a 2-hour glucose tolerance test glucose value of 140-199 mg/dL)
- Patient has failed surgical resection^ **-OR-** patient is not a candidate for surgical resection^
- All of the following if patient is a female of reproductive potential:
 - Baseline (within previous month) negative pregnancy test prior to start of therapy.
 - Must agree to use a non-hormonal medically acceptable method of contraception during and for one month after mifepristone therapy.
 - No history of unexplained vaginal bleeding.
 - Must not have endometrial hyperplasia with atypia or endometrial carcinoma.

Continued use criteria (12 months after initiation): Non-formulary **mifepristone (Korlym)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Documentation of at least one of the following:
 - Patient has improved glucose tolerance while on mifepristone therapy
 - Patient has stable glucose tolerance while on mifepristone therapy