Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE
mifepristone (Korlym®)

Initial approval 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
  -AND-
- Diagnosis of endogenous Cushing’s syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)
  -AND-
- 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)
  -AND-
- Patient has failed surgical resection^ -OR- patient is not a candidate for surgical resection^ 
  -AND-
- 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: Non-formulary mifepristone (Korlym®) will continue to be covered for 12 months on the prescription drug benefit 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

Note(s):
^ 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.

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