Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

KORLYM™ (mifepristone)

GPI CODING:

27304050000330

DESCRIPTION:

Korlym is a cortisol receptor blocker indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

APPROVAL DURATION:

Approval duration: 12 months

CRITERIA FOR KORLYM

I. Patient has a diagnosis of endogenous Cushing's syndrome **AND**
II. Korlym is prescribed by, or in consultation with, an endocrinologist **AND**
III. Patient has type 2 diabetes or glucose intolerance **AND**
IV. Korlym is used to control hyperglycemia secondary to hypercortisolism **AND**
V. Patient has had an inadequate or partial response to surgery OR there is a clinical reason that the patient has not had surgery **AND**
VI. Patient has tried and had an inadequate response to ketoconazole OR ketoconazole was not tolerated or is contraindicated **AND**
VII. Patient is not taking simvastatin, lovastatin, or a cytochrome P450 3A substrate with a narrow therapeutic range (eg, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, or tacrolimus) **AND**
VIII. Patient does not require concomitant treatment with systemic corticosteroids for a serious medical condition or illness (eg, immunosuppression after organ transplantation)
IX. Additional criteria for female patients only:
    A. Patient does not have endometrial hyperplasia with atypia, endometrial carcinoma, or a history of unexplained vaginal bleeding **AND**
    B. If patient is a women of childbearing potential:
        i. Pregnancy has been excluded before initiation of treatment and pregnancy will be excluded if treatment is interrupted for more than 14 days
        ii. Pregnancy will be prevented during treatment and for 1 month after stopping treatment by a non-hormonal contraceptive method (unless patient has had surgical sterilization