I. Requirements for Prior Authorization of Korlym

A. Prescriptions That Require Prior Authorization

All prescriptions for Korlym must be prior authorized.

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Korlym (mifepristone), the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Has a diagnosis of Cushing's syndrome and type 2 diabetes mellitus or glucose intolerance

AND

2. Is being prescribed Korlym by an endocrinologist

AND

3. Is 18 years of age or older

AND

4. Failed or is not a candidate for pituitary surgery

AND

5. Has a history of therapeutic failure, as documented by HbA1c, of ≥ 8 %, of:

    a. Insulin therapy

    OR

    b. Metformin at maximum tolerated doses in combination with the following at maximum tolerated doses:
        i. Insulin AND
        ii. Sulfonylurea AND
        iii. TZD AND
        iv. DPP-4 inhibitor OR GLP-1receptor agonist

AND

6. If female and did not have a surgical sterilization:

a. Had a negative pregnancy test prior to starting therapy with Korlym (mifepristone)

AND

b. Will be using a form of non-hormonal contraception

AND

7. Does not have a contraindication to Korlym (mifepristone)

OR

8. Does not meet the clinical review guidelines above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient**.**

FOR RENEWALS OF PRESCRIPTIONS FOR KORLYM: Requests for prior authorization of renewals of prescriptions for Korlym that were previously approved will take into account whether the recipient:

1. Does not have a contraindication to Korlym (mifepristone)

AND

2. If female and did not have a surgical sterilization, will be using a form of non-hormonal contraception

AND

3. Has improved glycemic control as evidenced by the recipient's HbA1c value

C Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Korlym. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

D. Dose and Duration of Therapy

Requests for prior authorization of Korlym will be approved as follows:

1. Initial approvals of requests for prior authorization of Korlym will be limited to 8 months of therapy

2. Renewals of requests for prior authorization of Korlym that were previously approved will be approved for up to 12 months of therapy

References:

1. Nieman, L.K. Epidemiology and clinical manifestations of Cushing's syndrome, UpToDate. Accessed July 6, 2012
2. Korlym package insert. Corcept Therapeutics Incorporated, Menlo Park, CA. February 2012
3. Inzucchi, S.E, et.al. “Management of hyperglycemia n type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Diabetes Association (EASD)”Diabetes Care. June 2012; 35 (1364-1379).