Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Korlym (mifepristone)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***March 2012 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Korlym (mifepristone).

Korlym (mifepristone) is a glucocorticoid receptor antagonist (GR-II) 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.

DEFINITIONS

ACTH – adrenocorticotropic hormone

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy &

Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Korlym (mifepristone), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with an endocrinologist
- Must be age 18 years or older
- Must have a diagnosis of hyperglycemia secondary to endogenous Cushing's syndrome
- Must have failed surgery or not be a candidate for surgery (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)
- Must meet all of the following:
    - Female members:
        - Must have a baseline (within previous month) negative pregnancy test prior to initiation of therapy if of reproductive potential. The date of the test must be provided.
        - Must use a non-hormonal medically acceptable method of contraception (unless surgically sterilized) during and for one month after mifepristone therapy if of reproductive potential
        - Must not have a history of unexplained vaginal bleeding
        - Must not have endometrial hyperplasia with atypia or endometrial carcinoma
    - Must not be on concomitant therapy with simvastatin, lovastatin, or CYP 3A substrates with a narrow therapeutic range (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus)
    - Must not be on concurrent long-term corticosteroid therapy
- Must have an adequate trial and failure of conventional anti-hyperglycemic medication. Chart documentation is required.
- Must have trial of ketoconazole or metyrapone therapy or have intolerance or contraindication to these medications
- Must have a baseline HbA1c level

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and the following criteria must be met:

- Must have documentation of improvement in hyperglycemia control as evidenced by a reduction in blood glucose levels, HbA1c, or anti-hyperglycemic medication doses or number of medications
- Must have documentation of a recent (within previous month) negative pregnancy test. The date of the test must be provided.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Korlym	120 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Korlym [package insert]. Corcept Therapeutics Inc., Menlo Park, CA, February 2012.
2. Johanssen S, Allolio B. Mifeprisone (RU 486) in Cushing's syndrome. European Journal of Endocrinology/European Federation of Endocrine Societies 2007; 157: 561-569.
3. Sartor O & Cutler GB Jr. Mifeprisone: treatment of Cushing's syndrome. Clinical Obstetrics and Gynecology 1996; 39: 506-510.
4. Chu JW, Matthias DF, Belanoff J, Schatzberg A, Hoffman AR & Feldman D. Successful long-term treatment of refractory Cushing's disease with high-dose mifepristone (RU 486). Journal of Clinical Endocrinology and Metabolism 2001; 86: 3568-3573.
5. Castinetti M, et al. Merits and pitfalls of mifepristone in Cushing's syndrome. European Journal of Endocrinology 2009; 160: 1003-1010.
6. Gaillard RC, Poffet, D, RiondelA & Saurat JH. RU 486 inhibits peripheral effects of glucocorticoids in humans. Journal of Clinical Endocrinology and Metabolism 1985; 61: 1009-1011.
7. Castinetti F, Conte-Devolx B, Brue T. Medical treatment of Cushing's syndrome: glucocorticoid receptor antagonists and mifepristone. Neuroendocrinology 2010; 92:125-130.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*