Pharmacy Medical Necessity Guidelines
Korlym™ (mifepristone)

Effective: 8/27/14

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OVERVIEW
FDA-APPROVED INDICATIONS
Korlym (mifepristone) 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.

Limitations of Use
Korlym (mifepristone) should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing’s syndrome.

A black box warning exists for Korlym (mifepristone), regarding termination of pregnancy. Korlym (mifepristone) has potent anti-progestational effects and will result in the termination of pregnancy. Pregnancy must be therefore excluded before the initiation of treatment with Korlym (mifepristone), or if treatment is interrupted for more than 14 days in females of reproductive potential.

Generally, the treatment of choice for ACTH-dependent Cushing’s syndrome is curative surgery with selective pituitary or ectopic corticotrophin tumor resection. Second-line treatments include more radical surgery, radiation therapy (for Cushing’s disease), medical therapy and bilateral adrenalectomy.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of Korlym (mifepristone) for members when all of the following criteria are met and limitations do not apply:
1. Documented diagnosis of Cushing’s syndrome AND
2. Documented diagnosis of Type 2 Diabetes or glucose intolerance AND
3. The Member has failed surgery to treat the condition (e.g., pituitary surgery, adrenal surgery) or is not a candidate for this type of surgery AND
4. The prescribing physician is an endocrinologist.

LIMITATIONS
1. Tufts Health Plan does not cover Korlym (mifepristone) for the treatment of patients with type 2 diabetes that is not secondary to Cushing’s syndrome.
2. Korlym (mifepristone) will not be approved if administered concomitantly with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus and tacrolimus).
3. Initial authorization will be limited to 3 months. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting efficacy.

CODES
None

REFERENCES


APPROVAL HISTORY

- June 12, 2014: Reviewed by the Pharmacy and Therapeutics Committee

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable *Member Handbook* and in coordination with the member’s physician(s). Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable *Member Handbook*. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For *Tufts Health Unify* (Medicare-Medicaid One Care for people ages 21 – 64), please refer to *Tufts Health Unify Prior Authorization Medical Necessity Guidelines*.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.