Reference number(s)
2160-A

SPECIALTY GUIDELINE MANAGEMENT

KORLYM (mifepristone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
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.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: pretreatment hemoglobin A1C level (for initial requests)

III. CRITERIA FOR INITIAL APPROVAL

Cushing's syndrome/disease
Authorization of 6 months may be granted for treatment of Cushing's syndrome/disease when all of the following criteria are met:
A. Member has type 2 diabetes mellitus or glucose intolerance
B. Korlym is being prescribed to control hyperglycemia secondary to hypercortisolism
C. Member has had surgery that was not curative OR member is not a candidate for surgery
D. If the member is able to become pregnant, a negative pregnancy test is required before initiating therapy

IV. CONTINUATION OF THERAPY

Cushing's syndrome/disease
Authorization of 12 months for continuation of therapy may be granted if the member has achieved or maintained adequate positive response, or there is improvement in signs and symptoms of the condition.

V. REFERENCES

1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics Incorporated; November 2019.
2. Nieman LK, Biller B, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100:2807-2831.