Reference number(s)
2160-A

Specialty Guideline Management mifepristone-Korlym

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Korlym	mifepristone

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 Indications[1,2]

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:

Should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Pretreatment cortisol level as measured by one of the following tests:
  - Urinary free cortisol (UFC)
  - Late-night salivary cortisol (LNSC)
  - 1 mg overnight dexamethasone suppression test (DST)
  - Longer, low dose DST (2 mg per day for 48 hours)
- Pretreatment hemoglobin A1C level, fasting plasma glucose or 2-hour plasma glucose (for initial requests)

Prescriber Specialties

This medication must be prescribed by or in consultation with an endocrinologist or a prescriber specialized in the treatment of endogenous Cushing's syndrome.

Coverage Criteria

Cushing's Syndrome/Disease[1-4]

Authorization of 12 months may be granted for treatment of Cushing's syndrome/disease in adult members when all of the following criteria are met:

- Member has a diagnosis of Cushing's syndrome/disease as evidenced by hypercortisolism per one of the following tests:
  - Urinary free cortisol (UFC)
  - Late-night salivary cortisol (LNSC)
  - 1 mg overnight dexamethasone suppression test (DST)
  - Longer, low dose DST (2 mg per day for 48 hours)
- Member has type 2 diabetes mellitus or glucose intolerance
- The requested drug is being prescribed to control hyperglycemia secondary to hypercortisolism
- Member has had surgery that was not curative OR member is not a candidate for surgery
- If the member is able to become pregnant, a negative pregnancy test is required before initiating therapy

Continuation of Therapy

Cushing's Syndrome/Disease[1-4]

Authorization of 12 months may be granted in adult members who have achieved or maintained an adequate positive response, or there is improvement in signs and symptoms of the condition.

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References

1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics Incorporated; September 2024.
2. Mifepristone [package insert]. Menlo Park, CA: Corcept Therapeutics Incorporated; September 2024.
3. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818.
4. Fleseriu M, Auchus R, Bancos I, et al. Consensus on Diagnosis and Management of Cushing's Disease: A Guideline Update. Lancet Diabetes Endocrinol. 2021;9(12):847-875. doi:10.1016/S2213-8587(21)00235-7.