CVS Caremark®

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| 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 Indications1,2

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 hemoglobin A1C level (for initial requests)

## Coverage Criteria

### Cushing’s Syndrome/Disease1-4

Authorization of 6 months may be granted for treatment of Cushing’s syndrome/disease when all of the following criteria are met:

* 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/Disease1-4

Authorization of 12 months may be granted if the member has achieved or maintained an adequate positive response, or there is improvement in signs and symptoms of the condition.

## 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