

Mifepristone 300mg Effective 11/01/2025 ☐ MassHealth UPPL Plan □ Prior Authorization ⊠Commercial/Exchange **Program Type** ☐ Quantity Limit □ Pharmacy Benefit ☐ Step Therapy **Benefit** ☐ Medical Benefit Specialty This medication has been designated specialty and must be filled at a contracted Limitations specialty pharmacy. **Medical and Specialty Medications** All Plans Phone: 877-519-1908 Fax: 855-540-3693 Contact Information **Non-Specialty Medications** All Plans Phone: 800-711-4555 Fax: 844-403-1029

Overview

Mifepristone (generic to 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. This agent should not be used for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

Coverage Guidelines

Exceptions

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following criteria are met:

- 1. Member is diagnosed hyperglycemia secondary to hypercortisolism with endogenous Cushing syndrome and type 2 diabetes mellitus or glucose intolerance
- 2. Member is 18 years of age or older

N/A

- 3. Member meets ONE of the following:
 - a. Member has failed surgical intervention (recurrence after surgery or failed tumor removal)
 - b. Surgical interventions are not appropriate for the member

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. Documentation member has had a positive clinical response to therapy.

Limitations

- 1. Initial approvals will be issued for 6 months
- 2. Reauthorization will be issued for 12 months
- 3. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Mifepristone 300mg tablet	4 tablets per day

References

- 1. Corcept Therapeutics Incorporated announces FDA approval of Korlym® (mifepristone) 300 mg tablets: first and only approved medication for Cushing's syndrome patients. February 17, 2012. Available at: http://www.corcept.com/news_events/view/pr_1329524335. Accessed 2015 Aug 10.
- 2. Fleseriu M, Biller BMK, Findling JW, Molitch ME, Schteingart DE, Gross C. Mifepristone, a glucocorticoid receptor antagonist produces clinical and metabolic benefits in patients with Cushing's syndrome. J Clin Endocrinol Metab. 2012;97(6):2039-49.
- 3. Katznelson L, Loriaux DL, Feldman D, Braunstein GD, Schteingart DE, Gross C. Global clinical response in Cushing's syndrome patients treated with mifepristone. Clinical Endocrinology. 2014;80(4):562-9.
- 4. Korlym (mifepristone) [prescribing information]. Menlo Park, CA: Corcept Therapeutics; September 2024.
- 5. Nieman LK, Biller BM, Findling JW, Newell-Price J, Savage MO, Stewart PM, et al. The diagnosis of Cushing's syndrome: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2008 May;93(5):1526-40.

Review History

2014 - Implemented

9/23/13 - Reviewed

9/22/14 - Reviewed

9/21/15 - Reviewed

9/19/16 - Reviewed

9/18/17 - Reviewed

9/24/18 - Reviewed

9/18/19 – Reviewed

7/22/20 – Reviewed and Updated July P&T Mtg; Updated Program Type to PA and QL. Effective 10/01/2020

9/16/20 - Reviewed at September P&T, Updated references.

9/22/2021 - Reviewed at P&T, no clinical changes. Separated Comm/Exch vs. MH.

2/14/2024- Reviewed at Feb P&T, Added generic Korlym to criteria. Effective ASAP

3/13/2024 - Reviewed at March P&T; Brand removed. Effective 4/1/24

08/13/2025 – Reviewed and Updated at August P&T. Updated initial criteria to remove previous trial requirements. Updated reauthorization criteria to require documentation of a positive clinical response to therapy. Effective 11/01/2025.

