

**Mifepristone 300mg**  
**Effective 04/01/2024**

|                              |  |                     |   |
|------------------------------|--|---------------------|---|
| <b>Plan</b>                  | <input type="checkbox"/> MassHealth UPPL<br><input checked="" type="checkbox"/> Commercial/Exchange  | <b>Program Type</b> | <input checked="" type="checkbox"/> Prior Authorization<br><input type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Benefit</b>               | <input checked="" type="checkbox"/> Pharmacy Benefit<br><input type="checkbox"/> Medical Benefit     |                     |   |
| <b>Specialty Limitations</b> | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. |                     |   |
| <b>Contact Information</b>   | <b>Medical and Specialty Medications</b>   |                     |   |
|                              | All Plans  | Phone: 877-519-1908 | Fax: 855-540-3693   |
| <b>Exceptions</b>            | <b>Non-Specialty Medications</b>   |                     |   |
|                              | All Plans  | Phone: 800-711-4555 | Fax: 844-403-1029   |
| <b>Exceptions</b>            | N/A  |                     |   |

**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

**Coverage Guidelines**

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

**OR**

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

1. The member is diagnosed hyperglycemia secondary to hypercortisolism with endogenous Cushing syndrome who have type 2 diabetes mellitus or glucose intolerance
2. The member is  $\geq 18$  years of age
3. The member has had an inadequate response or adverse reaction to one or contraindication to both of the following: ketoconazole tablets, Lysodren tablets.
4. The member has failed surgical intervention (recurrence after surgery or failed tumor removal) **OR**
5. Surgical interventions are not appropriate.

**Continuation of Therapy**

Reauthorization requires clinical documentation of clinical response.

**Limitations**

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

|                    |                         |
|--------------------|-------------------------|
| Mifepristone 300mg | 120 tablets per 30 days |
|--------------------|-------------------------|

## References

1. Korlym (mifepristone) [prescribing information]. Menlo Park, CA: Corcept Therapeutics; November 2019
2. 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](http://www.corcept.com/news_events/view/pr_1329524335). Accessed 2015 Aug 10.
3. 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.
4. 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.
5. 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.
6. Nieman LK. Medical therapy of hypercortisolism(Cushing's syndrome). In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): Available at: <http://www.utdol.com/utd/index.do>

## 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

