BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Korlym

Policy Number: 9.303
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Korlym (mifepristone)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. Diagnosis of endogenous Cushing's syndrome; ***AND*** 2. Diagnosis of type 2 Diabetes or glucose intolerance; ***AND*** 3. Have failed surgery or are not candidates for surgery; ***AND*** 4. Pregnancy has been excluded.
Age Restriction	None
Prescriber	The prescribing practitioner is an endocrinologist certified to prescribe Korlym

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Restriction	
Coverage Duration	12 months
Reauthorization Criteria	1. Patient is continually monitored for improved symptoms (i.e. HbA1c, Body weight and Cushingoid appearance).

Clinical Background Information and 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 2012. Available at: https://www.korlym.com/. Accessed March 2012.
2. Fleseriu M, Biller BM, Findling JW, Molitch ME, Schteingart DE, and Coleman G. Mifepristone, a glucocorticoid receptor antagonist, produces clinical and metabolic benefits in patients with Cushing's Syndrome. J Clin Endocrinol Metab 2012; 97:2039-2049.
3. Korlym® prescribing information Corcept Therapeutics Incorporated. Menlo Park, CA. 2013.
4. Mancini T, Porcelli T, Giustina A. Treatment of Cushing disease: overview and recent findings. Ther Clin Risk Manag. 2010 Oct 21;6:505-16.
5. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically [cited 2012 Mar]. Available from: http://www.thomsonhc.com/.
6. Mifeprex® prescribing information. Danco Laboratories. New York, NY. 2005.
7. 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.
8. Nieman K. Medical therapy of hypercortisolism (Cushing's syndrome). In: Basow DS (Ed). UpToDate [database on the internet]. Available at: http://www.utdol.com/utd/index.do. Accessed March 2012.
9. SIGNIFOR prescribing information. Novartis. East Hanover, NJ. December 2012.
10. Feelders R, Hofland L. Update: Medical Treatment of Cushing's Disease. J Clin Endocrinol Metab 2013; 98: 425-438

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.037 Korlym Policy retired, new policy created	1/1/2021	P&T Committee

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.