CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Korlym (mifepristone)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

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. It is a selective antagonist of the progesterone receptor at low doses and blocks the glucocorticoid receptor (GR-II) at higher doses. Korlym does not reduce cortisol levels.
Glucose intolerance is common in Cushing's syndrome, primarily due to stimulation of gluconeogenesis by excess cortisol. Controlling hypercortisolism is the first step taken to improve glucose metabolism in these patients, before the addition of antidiabetic medication such as metformin. Impaired glucose metabolism is generally resolved once cortisol levels have normalized, however, patients with diabetes should continue antidiabetic therapy.

Korlym (mifepristone) will be considered for coverage when the following criteria are met:

Cushing's Syndrome

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has diagnoses of endogenous Cushing's syndrome AND type 2 diabetes or glucose intolerance secondary to hypercortisolism (baseline labs required); AND
4. Member failed surgery or is not a candidate for surgery (documentation required); AND
5. Member has tried and failed ketoconazole and/or cabergoline for at least 3 months[2,5]; AND
6. Female members with reproductive potential must have a negative pregnancy test.
7. **Dosage allowed/Quantity limit:** Start 300 mg orally once daily; titrate as needed per package insert up to 20mg/kg or 1200mg (4 tablets) once daily. (QL 120 tablets per 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes documenting sustained improvement of glucose control compared to pre-treatment (i.e. decreased HbA1c and/or fasting glucose from baseline, reduced use of antidiabetic medications)

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Korlym (mifepristone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/01/2020	New policy for Korlym created.
03/28/2022	Transferred to new template. Added new reference. Elaborated dosing information.

References:

1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics Incorporated; 2019.
2. 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
3. Fleseriu M, Biller BM, Findling JW, et al. Mifepristone, a glucocorticoid receptor antagonist, produces clinical and metabolic benefits in patients with Cushing's syndrome. *J Clin Endocrinol Metab*. 2012;97(6):2039-2049. doi:10.1210/jc.2011-3350
4. Mazziotti G, Gazzaruso C, Giustina A. Diabetes in Cushing syndrome: basic and clinical aspects. *Trends Endocrinol Metab*. 2011;22(12):499-506. doi:10.1016/j.tem.2011.09.001
5. Scaroni C, Zilio M, Foti M, Boscaro M. Glucose Metabolism Abnormalities in Cushing Syndrome: From Molecular Basis to Clinical Management. *Endocrine Reviews*. 2017;38(3):189-219. doi:10.1210/er.2016-1105
6. 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

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