Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

Cushing's Disease Agents: Korlym® (mifepristone), Recorlev® (levoketoconazole)

Effective: January 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Korlym (mifepristone) 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. Korlym (mifepristone) should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

Recorlev (levoketoconazole) is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolism in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

Clinical Guideline Coverage Criteria

Korlym (mifepristone)

The plan may authorization coverage of Korlym for Members when all of the following criteria are met

Initial Authorization Criteria

1. Documented diagnosis of hyperglycemia secondary to endogenous Cushing's disease

AND

2. Documented diagnosis of type 2 diabetes or glucose intolerance

AND

3. The patient is 18 years of age or older

AND

4. The prescribing physician is an endocrinologist

AND

5. Documentation of **one (1)** of the following:
    a. Surgery (e.g., pituitary, adrenal) is not an option for the patient
    b. Surgery (e.g., pituitary, adrenal) has not been curative for the patient

Reauthorization Criteria

1. Documented diagnosis of hyperglycemia secondary to endogenous Cushing's disease

AND

2. Documented diagnosis of type 2 diabetes or glucose intolerance

AND

3. The patient is 18 years of age or older

AND

4. The prescribing physician is an endocrinologist

AND

5. Documentation of improved or stable glucose tolerance

Recorlev (levoketoconazole)

The plan may authorization coverage of Recorlev for Members when all of the following criteria are met

Initial Authorization Criteria

1. Documented diagnosis of hypercortisolemia secondary to Cushing's disease

AND

2. The patient is 18 years of age or older

AND

3. The prescribing physician is an endocrinologist

AND

4. Documentation of **one (1)** of the following:
    a. Surgery (e.g., pituitary, adrenal) is not an option for the patient
    b. Surgery (e.g., pituitary, adrenal) has not been curative for the patient

Reauthorization Criteria

1. Documented diagnosis of hypercortisolemia secondary to Cushing's disease

AND

2. The patient is 18 years of age or older

AND

3. The prescribing physician is an endocrinologist

AND

4. Documentation of a reduction in baseline 24-hour urinary free cortisol levels

Limitations

1. Initial coverage of a Cushing's Disease Agent will be authorized for three (3) months. Reauthorization of a Cushing's Disease Agent will be provided for 12-month intervals,
2. Members new to the plan stable on a Cushing's Disease Agent should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

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3. Colao A, Petersen S, Newell-Price J, et al. A 12-month phase 3 study of pasireotide in Cushing's disease. N Engl J Med. 2012; 366:914-24.

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14. Torre JJ, Bloomgarden JT, Dickey RA, et al. American association of clinical endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of hypertension. Endocr Pract. 2006; 12:193-222.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- August 8, 2023: No changes
- October 8, 2024: Remove Isturisa due to coverage moving to non-formulary status effective 1/1/25 (eff 1/1/2025)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.