Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy

CENTENE® Corporation

Clinical Policy: Relacorilant

Reference Number: CP.PHAR.736
Effective Date: FDA Approval Date
Last Review Date: 08.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Relacorilant (Brand Name®/™) is a selective cortisol modulator.

FDA Approved Indication(s) [Pending]

Relacorilant is indicated for the treatment of patients with endogenous hypercortisolism (Cushing's syndrome).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that relacorilant is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Cushing's Syndrome (must meet all)**:**

1. Diagnosis of Cushing's syndrome;*
2. Member has one of the following (a, b, or c):*
   a. Type 2 diabetes mellitus;
   b. Impaired glucose tolerance as evidenced by plasma glucose ≥ 140 and < 200 mg/dL on 2-hour oral glucose tolerance test in the last 30 days;
   c. Uncontrolled hypertension as evidenced by one of the following in the last 30 days (i or ii):
      i. Mean systolic blood pressure ≥ 135 to ≤ 170 mmHg;
      ii. Mean diastolic blood pressure ≥ 85 to ≤ 110 mmHg;
3. Prescribed by or in consultation with an endocrinologist;
4. Age ≥ 18 years;*
5. Member meets one of the following (a or b):*
   a. Surgery was not curative;
   b. Member is not eligible for surgery;
6. Dose does not exceed 400 mg per day.*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Cushing's Syndrome (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy (*see Appendix D*);
3. If request is for a dose increase, new dose does not exceed 400 mg per day.*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
UFC: urinary free cortisol

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings [Pending]
- Contraindication(s): pending
- Boxed warning(s): pending

Appendix D: General Information
- Positive treatment response for Cushing's syndrome includes, but is not limited to, normalization of cortisol levels or action at its receptors to eliminate signs and symptoms of the disease. A 24-hour urinary free cortisol (UFC) level may be used to assess normalization of cortisol levels. The American Association of Neurological Surgeons notes that UFC levels higher than 50-100 mcg/24 h in adults suggest the presence of Cushing's syndrome. Dexamethasone suppression test or late night salivary cortisol concentrations may also be used to assess normalization of cortisol levels.
- Positive treatment response for hypertension includes, but is not limited to, decrease in mean systolic or diastolic blood pressure.
- Positive treatment response for type 2 diabetes mellitus or impaired glucose tolerance includes, but is not limited to, decrease in hemoglobin A1c (HbA1c), normalization or decrease in plasma glucose value on oral glucose tolerance test, and decrease in daily insulin or sulfonylurea doses.

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
Cushing's syndrome*	100 mg PO QD initially, increased sequentially to a target dose of 400 mg PO QD*	400 mg/day*

VI. Product Availability [Pending]
Capsule: 100 mg*

VII. References

1. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's syndrome: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100:2807.
2. Fleseriu M, Auchus R, Bancos I, et al. Consensus on diagnosis and management of Cushing's disease: a guideline update. Lancet Diabetes Endocrinol. 2021 Dec; 9(12): 847-875.
3. ClinicalTrials.gov. Corcept Therapeutics. A study of the efficacy and safety of relacorilant in patients with endogenous Cushing syndrome (GRACE). Available at: https://clinicaltrials.gov/study/NCT03697109. Accessed April 2, 2025.
4. Pivonello R, Munster PM, Terzolo M, et al. Medical treatment of hypercortisolism with relacorilant: Final results of the phase 3 GRACE study. Slide presentation available at: https://corcept.com/wp-content/uploads/HiD2024-GRACE-presentation2.pdf. Accessed April 2, 2025.
5. ClinicalTrials.gov. Corcept Therapeutics. Efficacy and safety of relacorilant in patients with cortisol-secreting adrenal adenomas (GRADIENT). Available at: https://clinicaltrials.gov/study/NCT04308590. Accessed April 2, 2025.
6. Auchus RJ, Grauer A, Moraitis AG. GRADIENT: A phase 3, double-blind, randomized, placebo-controlled study to assess the efficacy and safety of a selective glucocorticoid receptor modulator, relacorilant, in patients with autonomous cortisol secretion due to cortisol-secreting adrenal adenoma(s)/hyperplasia. Poster presentation available at: https://corcept.com/wp-content/uploads/2020/03/82533-ENDO-Poster-2020-03-27-final-1.pdf. Accessed April 2, 2025.
7. ClinicalTrials.gov. Corcept Therapeutics. Study to evaluate CORT125134 in participants with Cushing's syndrome. Available at: https://clinicaltrials.gov/study/NCT02804750. Accessed April 2, 2025.
8. Pivonello R, Bancos I, Feelders RA, et al. Relacorilant, a selective glucocorticoid receptor modulator, induces clinical improvements in patients with Cushing syndrome: Results from a prospective, open-label phase 2 study. Front Endocrinol (Lausanne). 2021 Jul 14; 12: 662865. doi: 10.3389/fendo.2021.662865
9. ClinicalTrials.gov. Corcept Therapeutics. Extension study to evaluate the safety of long-term use of relacorilant in patients with Cushing syndrome. Available at: https://clinicaltrials.gov/study/NCT03604198. Accessed April 2, 2025.
10. Auchus RJ, Gills-Januszewska A, Badiu C, et al. Relacorilant improved blood pressure and maintained other cardiometabolic improvements in long-term study in patients with endogenous hypercortisolism (Cushing syndrome). Presented at 22nd World Congress Insulin Resistance, Diabetes, & Cardiovascular Disease, December 12-14, 2024; Universal City, CA. Available at: https://corcept.com/wp-content/uploads/Auchus-WCIRDC2024-Study-452-presentation-web.pdf. Accessed April 2, 2025.

Coding Implications [Pending]

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Pending	Pending

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	04.02.25	08.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.