Clinical Policy: Relacorilant (Lifyorli)

Reference Number: CP.PHAR.736
Effective Date: 06.01.26
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

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

Description

Relacorilant (Lifyorli™) is a glucocorticoid receptor antagonist.

FDA Approved Indication(s)

Lifyorli is indicated in combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab.

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 Lifyorli is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (must meet all)**:**

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is platinum-resistant (i.e., disease progressed < 6 months from completion of a platinum-containing therapy);
5. Member has received 1 to 3 prior systemic treatment regimens, at least one of which included bevacizumab (*see Appendix B for examples*);
6. Lifyorli is not prescribed concurrently with systemic glucocorticoids used for a lifesaving indication (e.g., immunosuppression after organ transplantation);
7. Prescribed in combination with nab-paclitaxel;
8. Request does not exceed any of the following (a, b, and c):
   a. 150 mg on the day before, the day of, and the day after each nab-paclitaxel infusion;
   b. 3 capsules per dose;
   c. 9 doses per 28 days;
9. Dose is at least 125 mg per dose.

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/ICHRA) 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/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA, 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/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Lifyorli for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Prescribed in combination with nab-paclitaxel;
4. If request is for a dose increase, request does not exceed any of the following (a, b, and c):
   a. 150 mg on the day before, the day of, and the day after each nab-paclitaxel infusion;
   b. 3 capsules per dose;
   c. 9 doses per 28 days;
5. Dose is at least 125 mg per dose.

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/ICHRA) 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/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA, 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/ICHRA, 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/ICHRA, 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

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name – Examples of Systemic Therapies	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin/paclitaxel ± bevacizumab	Varies	Varies
paclitaxel/cisplatin	Varies	Varies
carboplatin/doxorubicin	Varies	Varies
docetaxel/carboplatin ± bevacizumab	Varies	Varies
fluorouracil/oxaliplatin/leucovorin ± bevacizumab	Varies	Varies
capecitabine/oxaliplatin ± bevacizumab	Varies	Varies
cyclophosphamide/bevacizumab	Varies	Varies
docetaxel	Varies	Varies
etoposide	Varies	Varies
gemcitabine	Varies	Varies
doxorubicin ± bevacizumab	Varies	Varies
topotecan	Varies	Varies
capecitabine	Varies	Varies
pemetrexed	Varies	Varies
vinorelbine	Varies	Varies
ifosfamide	Varies	Varies
irinotecan	Varies	Varies
melphalan	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concurrent systemic glucocorticoid therapy for a lifesaving indication

- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Epithelial ovarian, fallopian tube, and primary peritoneal cancer	150 mg* PO once on the day before, the day of, and the day after each nab-paclitaxel infusion. Nab-paclitaxel is recommended to be administered on days 1, 8, and 15 of each 28-day cycle **May be reduced to 125 mg for adverse reactions; if patients are unable to tolerate after one dose reduction, permanently discontinue Lifyorli*	150 mg/dose

VI. Product Availability

Capsules: 25 mg, 100 mg

VII. References

1. Lifyorli Prescribing Information. Redwood City, CA: Corcept Therapeutics Incorporated; March 2026. Available at: www.lifyorli.com. Accessed April 1, 2026.
2. Olawaiye AB, Gladieff L, O'Malley DM, et al. Relacorilant and nab-paclitaxel in patients with platinum-resistant ovarian cancer (ROSELLA): An open-label, randomised, controlled, phase 3 trial. Lancet. 2025; 405(10496): 2205-2216.
3. National Comprehensive Cancer Network. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer Version 3.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed April 1, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Drug is now FDA approved (adopted from CP.PHAR.736_PEPP) – criteria added for new indication of ovarian cancer.	04.01.26	05.26

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.