

CHECKLIST TO PREPARE

Letters of Medical Exception, Medical Necessity, and Appeal

This checklist serves as a resource when completing a letter of medical exception, medical necessity, or appeal following a denial of coverage. Using this checklist does not guarantee coverage and should not be a substitute for, or influence on, the independent medical judgment of the healthcare provider. As a reminder, the final letter should be printed on the physician's official letterhead.

✓ Provide complete patient information

- Patient demographics
- Diagnosis:
 - Include the **date** they were diagnosed with platinum-resistant ovarian cancer
- ICD-10-CM code(s):
 - Insert appropriate ICD-10-CM code(s) specific to platinum-resistant ovarian cancer
 - Call out platinum-resistant ovarian cancer diagnosis

✓ Attach supporting documentation

- LIFYORLI Prescribing Information
- LIFYORLI FDA approval letter
- Clinical notes/medical records
- Letter of denial (if applicable)
- Clinical trial publication(s)
- Peer-reviewed literature
- Evidence-based clinical guidelines
- Front-and-back copies of your patient's insurance card(s)

✓ Include patient's medical history to support treatment rationale

- **Severity of patient's condition:**
Eg, clinical outcomes measures, pathology reports, ECOG performance status
- **Previous treatments or step therapies:**
A detailed list of 1-3 prior systemic treatments, at least 1 of which included bevacizumab. Specify drug names and duration, responses to those treatments, and reason for discontinuation
- **Patient's disease progression:**
Eg, proof of platinum-resistance, defined as disease progression ≤6 months from completion of platinum-containing therapy
- **Other relevant medical history:**
Include information such as histologic confirmation of diagnosis, intolerance to other approved therapies (eg, bevacizumab), other factors impacting treatment
- If insurance has denied coverage, include the reason for the denial

Refer to your patient's insurance provider or health plan for specific forms or requirements:

Ensure your office is tracking coverage of nab-paclitaxel and include any relevant documentation

Restate why LIFYORLI + nab-paclitaxel is a medically appropriate and necessary treatment for your patient.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Ovarian Cancer recommend relacorilant (LIFYORLI) in combination with nab-paclitaxel as a preferred therapy for select patients with platinum-resistant disease.^{1*}

ECOG, Eastern Cooperative Oncology Group; FDA, US Food and Drug Administration; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*; NCCN, National Comprehensive Cancer Network[®] (NCCN[®]).

*NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.¹

Reference: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer V.4.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed April 13, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org.

Please see Important Safety Information on next page and the accompanying full [Prescribing Information](#).

For more information, call LIFYORLI Support™ at 1-85-LIFYORLI (1-855-439-6754), Monday-Friday, 8 AM-8 PM ET, or visit LIFYORLIhcp.com/support.



INDICATIONS & USAGE

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 1-3 prior systemic treatment regimens, at least one of which included bevacizumab.

IMPORTANT SAFETY INFORMATION

Contraindications: LIFYORLI is contraindicated in patients receiving systemic glucocorticoids for lifesaving purposes (e.g., immunosuppression after organ transplantation) because LIFYORLI antagonizes the effect of glucocorticoids.

Warnings and Precautions:

Neutropenia and Severe Infections: LIFYORLI in combination with nab-paclitaxel can cause neutropenia, including febrile neutropenia and severe infections. There was one fatal event of septic shock with febrile neutropenia. Monitor complete blood counts prior to each weekly treatment with LIFYORLI in combination with nab-paclitaxel and as clinically indicated. Withhold dose, reduce dose, or permanently discontinue LIFYORLI based on severity.

Adrenal Insufficiency: LIFYORLI can cause adrenal insufficiency. Adrenal insufficiency can occur at any time during treatment with LIFYORLI. Monitor for signs and symptoms of adrenal insufficiency. Withhold LIFYORLI and administer glucocorticoid therapy if adrenal insufficiency is suspected. After resolution of adrenal insufficiency, resume previous dose, reduce dose, or permanently discontinue LIFYORLI based on severity.

Exacerbation of Conditions Treated with Glucocorticoids:

Use of LIFYORLI in patients taking systemic glucocorticoids for other conditions (e.g., autoimmune disorders) may exacerbate these conditions. LIFYORLI may make systemic glucocorticoids less effective and coadministration of systemic glucocorticoids may make LIFYORLI less effective. Monitor patients for reduced effectiveness of LIFYORLI and glucocorticoids in patients receiving both.

Embryo-Fetal Toxicity: LIFYORLI can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the risk to a fetus and to use effective contraception.

Adverse Reactions:

Serious adverse reactions ($\geq 2\%$) in patients who received LIFYORLI plus nab-paclitaxel were neutropenia, pneumonia, pleural effusion, febrile neutropenia, and fatigue. Fatal adverse reactions (2.1%) were septic shock, cardiac arrest, ischemic stroke, and intestinal perforation.

The adverse reaction ($>2\%$) that resulted in permanent discontinuation of LIFYORLI in patients was intestinal obstruction. Adverse reactions ($\geq 5\%$) that required dosage interruptions of LIFYORLI in combination with nab-paclitaxel in patients included neutropenia, anemia, and fatigue. Adverse reactions requiring dose reductions of LIFYORLI included fatigue, decreased appetite, abdominal pain, neutropenia, edema, and sciatica.

The most common adverse reactions ($>20\%$) in patients who received LIFYORLI plus nab-paclitaxel, including laboratory abnormalities, were decreased hemoglobin, decreased neutrophils, fatigue, nausea, diarrhea, decreased platelets, rash, and decreased appetite.

Drug Interactions:

- **Strong CYP3A Inducers:** Avoid coadministration of LIFYORLI plus nab-paclitaxel with strong CYP3A inducers.
- **CYP2C8 Inducers and Moderate CYP3A Inducers:** Monitor for reduced effectiveness of LIFYORLI plus nab-paclitaxel with CYP2C8 inducers and moderate CYP3A inducers.
- **CYP2C8 Inhibitors:** Monitor for increased adverse reactions and modify the dosage for adverse reactions as recommended.
- **CYP3A Substrates:** Avoid concomitant use unless otherwise recommended in the Prescribing Information for CYP3A substrates.
- **Certain CYP2C8 Substrates:** Avoid concomitant use unless otherwise recommended in the Prescribing Information for CYP2C8 substrates.

Use in Specific Populations:

- **Lactation:** Advise women not to breastfeed during treatment with LIFYORLI and for 1 week after the last dose.
- **Geriatric Use:** A higher incidence of grade 3-4 adverse events and dosage modification occurred in patients aged ≥ 65 years compared to younger adult patients.
- **Hepatic Impairment:** Avoid LIFYORLI in combination with nab-paclitaxel in patients with moderate or severe hepatic impairment.

Please see the accompanying full [Prescribing Information](#) for additional Important Safety Information.



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