Lifyorli™
(relacorilant) 100 mg, 25 mg capsules

+ nab-paclitaxel

Billing and Coding Guide

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.

SELECT IMPORTANT SAFETY INFORMATION

The labeling for LIFYORLI contains warnings and precautions for neutropenia and severe infections, adrenal insufficiency, exacerbation of conditions treated with glucocorticoids, and embryo-fetal toxicity. Serious adverse reactions (≥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 most common adverse reactions (>20%), including laboratory abnormalities, were decreased hemoglobin, decreased neutrophils, fatigue, nausea, diarrhea, decreased platelets, rash, and decreased appetite.

Please see additional Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™
(relacorilant) 100 mg, 25 mg capsules

This resource provides information about LIFYORLI (relacorilant) + nab-paclitaxel, including:

- **Coding descriptors** that capture information needed for billing and coding of LIFYORLI and nab-paclitaxel, such as:
  - Diagnoses, medical procedures, and product information
- A list of **specialty distributors** authorized to distribute LIFYORLI to qualified accounts
- Our **specialty pharmacy** network that can dispense LIFYORLI for this combination regimen

 Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Table of Contents

PAGE 4 **LIFYORLI (relacorilant) + nab-paclitaxel Indications and Dosage and Administration**

- Indications
- Dosage and administration

PAGE 5 **Nab-paclitaxel Product Information**

- How nab-paclitaxel is supplied
- Nab-paclitaxel storage

PAGE 6 **Coding Procedures**

- ICD-10-CM codes for platinum-resistant ovarian cancer
- Coding for nab-paclitaxel
  CPT® codes | Revenue codes | HCPCS codes | 5010 electronic transaction coding

PAGE 11 **Completing a CMS-1500 Form for nab-paclitaxel Reimbursement**

PAGE 12 **Completing a CMS-1450 (UB-04) Form for nab-paclitaxel Reimbursement**

PAGE 13 **LIFYORLI Product Information**

- How LIFYORLI is supplied
- LIFYORLI storage

PAGE 14 **Acquiring LIFYORLI + nab-paclitaxel**

- LIFYORLI authorized specialty distributors
- LIFYORLI specialty pharmacy network

PAGE 15 **LIFYORLI Support™ and Other Helpful Resources**

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

LIFYORLI (relacorilant) + nab-paclitaxel Indications and Dosage and Administration

Indications

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 1 of which included bevacizumab.[1]

Dosage and administration[1]

The dosing regimen for LIFYORLI is **3 softgel capsules taken orally, once daily for 3 consecutive days:** the day before, the day of, and the day after each weekly nab-paclitaxel infusion. This schedule is followed for 3 weeks during each 28-day cycle. The recommended dose for LIFYORLI is 150 mg.

The **recommended dose for nab-paclitaxel is 80-mg/m^2 intravenous (IV) infusion** on Days 1, 8, and 15 of each 28-day cycle.

Note: The dosage for nab-paclitaxel with LIFYORLI is **lower** than if nab-paclitaxel is administered as a single-agent therapy.[1,2]*

Continue treatment with LIFYORLI + nab-paclitaxel until disease progression or unacceptable toxicity.

See the LIFYORLI Prescribing Information for full dosing information, including dose modification instructions for LIFYORLI and nab-paclitaxel.

*Nab-paclitaxel is dosed at approximately 80 mg/m^2 by IV infusion on Day 1, Day 8, and Day 15 of a 28-day cycle, when combined with LIFYORLI, a CYP3A inhibitor.[1] The 80-mg/m^2 dose of nab-paclitaxel, in combination with LIFYORLI, provided exposure comparable to the 100-mg/m^2 monotherapy dose in the phase 2 study.[1,3,4]

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

Nab-paclitaxel Product Information

Nab-paclitaxel* is a microtubule inhibitor administered through IV infusion for the treatment of platinum-resistant epithelial ovarian, fallopian tube, and primary peritoneal cancer in combination with LIFYORLI (relacorilant).[1,2,5]

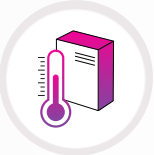
*PAClitaxel protein-bound particles (nab-paclitaxel) infusion.

How nab-paclitaxel is supplied[5]

Not scaled to actual size.

- **Nab-paclitaxel for injectable suspension** is a white to yellow, sterile, lyophilized powder supplied as 100 mg of paclitaxel in a single-dose vial, individually packaged in a carton
- Because nab-paclitaxel is available from more than 1 manufacturer, be sure to **review the medication's label for the corresponding NDC**

Nab-paclitaxel storage[5]



- Store the vials in original cartons at 20°C to 25°C (68°F to 77°F)
- Retain in the original package to protect from bright light
- Nab-paclitaxel is a hazardous drug. Follow applicable special handling and disposal procedures

IV, intravenous; NDC, National Drug Code.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

Coding Procedures

The coding information discussed in the following sections is provided for informational purposes only, is subject to change, and should not be construed as legal advice. These codes may not apply to all patients or to all health plans. Conversely, additional codes not listed in this guide may apply to some patients. Providers should follow payer-specific coding requirements and exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient. Information provided in this guide is effective as of 03/2026.

ICD-10-CM codes for platinum-resistant ovarian cancer

Your patient's diagnosis must be accurately documented. This includes providing appropriate ICD-10-CM codes. Incorrect or insufficient coding for platinum-resistant ovarian cancer may result in an insurance denial and/or a reimbursement claim denial.

While there is currently no ICD-10-CM code available specifically for a diagnosis of platinum-resistant ovarian cancer, 1 or more of the example ICD-10-CM codes shown on the next page may be used to help appropriately document your patient's diagnosis.

ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification.*

Coding Procedures (cont'd)

ICD-10-CM codes for platinum-resistant ovarian cancer (cont'd)

Epithelial ovarian, fallopian tube, or primary peritoneal cancer[6]	
ICD-10-CM code	Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified

ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification.*

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

Coding Procedures (cont'd)

Coding for nab-paclitaxel

When administered in combination with LIFYORLI (relacorilant) for the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, nab-paclitaxel is dosed at 80 mg/m^2.[1]

Note: 80-mg/m^2 IV infusion over 30-40 minutes on Day 1, Day 8, and Day 15 of a 28-day cycle. When combined with LIFYORLI, a CYP3A inhibitor, nab-paclitaxel is dosed at approximately 80 mg/m^2. The 80-mg/m^2 dose of nab-paclitaxel, in combination with LIFYORLI, provided exposure comparable to the 100-mg/m^2 monotherapy dose in the phase 2 study.[1,3-5]

CPT® codes

CPT codes are used to indicate which medical services and procedures were performed on a patient and/or how a drug or medical supply was administered.

Healthcare providers are required to report the administration of an IV infusion of nab-paclitaxel. The service may be documented using the CPT code below.[7]

CPT code	Description
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug

Revenue codes

The following revenue codes may be recorded on the CMS-1450 (UB-04) form when billing hospital outpatient claims.[8]

Revenue codes	Description
0250	General pharmacy
0258	IV solutions; paclitaxel protein-bound particles administration
0260	IV therapy (required by Medicare for separate billable drugs)
0636	Pharmacy—drugs requiring detailed coding; may be used to specify paclitaxel protein-bound particles as the drug given

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in Field 42 of the CMS-1450 (UB-04) form. (See example form on page 12 for more information.)

CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; IV, intravenous.

Coding Procedures (cont'd)

Coding for nab-paclitaxel (cont'd)

HCPCS codes

J-codes are permanent codes used by hospitals, physicians, and other health professionals who bill Medicare, Medicaid, and commercial payers for non-orally administered medication and chemotherapy drugs.

The following HCPCS J-code below should be used for nab-paclitaxel[9]:

HCPCS code	Description
J9264	Injection, paclitaxel protein-bound particles, 1 mg

Billing unit conversion			
1 mg	1 unit	100-mg vial	100 units

CMS and most payers require prescribers to record drug wastage or lack thereof.

Current CMS policy for outpatient or office-administered drugs permits billing for the entire vial **even if the entire contents are not used**, but only if the unused portion is discarded and it is appropriately documented.[10]

The discarded amount is billed on a second claim line with a JW modifier. **For instance, if you administer 80 units of a 100-mg vial, a JW modifier should be added to indicate unused drug or biologic from a single-use vial when the remainder is discarded (ie, J9264-JW).** Include a JZ modifier to report no discarded drug (ie, J9264-JZ)[11,12]

Reminder: When administered in combination with LIFYORLI (relacorilant) for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1-3 prior systemic treatment regimens, at least 1 of which included bevacizumab, nab-paclitaxel is dosed at 80 mg/m^2 vs 100 mg/m^2 when used as monotherapy. Therefore, it is important to include the JW modifier on claims to bill for the discarded drug.[1]

CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

Coding Procedures (cont'd)

Coding for nab-paclitaxel (cont'd)

5010 electronic transaction coding

- When submitting electronic claims using 837P or 837I digital forms, the 11-digit NDC is preceded by the qualifier N4, if it is required by the payer[12,13]
- Following the N4 qualifier, you would typically include the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or mL (milliliter), and the quantity administered[13,14]

5010 transaction coding for nab-paclitaxel[12-15]

Category	Loop ID	Segment	Electronic description	Example	Requirements
National Drug Code	2410	LIN02	Product ID qualifier	N4	N4=NDC in 5-4-2 format
		LIN03	NDC	11-digit zero-filled nab-paclitaxel NDC # (XXXXX-0XXX-XX)	NDC
Drug quantity	2410	CTP04	Quantity (ie, number of units)	100	Unit count per procedure code
		CTP05-1	Code qualifier	UN	F2=international unit, GR=gram, ME=milligram mL=milliliter, and UN=unit

According to the table above, an example segment on an electronic claim submission line would look like this (with the appropriate NDC inputted following the N4 qualifier)[12-15]*:

N4XXXXX0XXXXX UN100

NDC, National Drug Code.

*This is an example to demonstrate NDC quantity reporting for one 100-unit vial of paclitaxel. The actual amount of drug used can vary based on factors, such as patient weight. Please note, the Xs should be replaced with the actual NDC for the nab-paclitaxel used plus the addition of the zero for billing as shown in the table and example. NDC quantity reporting procedures vary among payers. Therefore, the provider should consult each specific payer to determine the required format.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

Completing a CMS-1500 Form for nab-paclitaxel Reimbursement

The CMS-1500 form is used when billing in-office claims. The sample annotated form below provides guidance on completing a CMS-1500 form by populating fields that health plans require for nab-paclitaxel reimbursement.

Please confirm the accuracy of the codes you use to bill for nab-paclitaxel with each payer. If submitting to a Medicare Administrative Contractor (MAC), refer to the specific MAC's guidelines for completion of the reimbursement forms. **This sample claim form is intended for use only as a reference. The codes provided are subject to change and should not be construed as legal or billing advice.**

ITEM 19 Many payers require detailed information about the medication in Item 19. Typically, payers require the medication name, total dosage and strength, route of administration, and 11-digit NDC.[16,17]

ITEM 21 Indicate appropriate diagnosis using ICD-10-CM code(s).[16]

ITEM 24A Enter a 6-digit or 8-digit (month-day-year) date for each procedure, service, or supply. Include NDC, if required, in the shaded red areas above each date.[16]

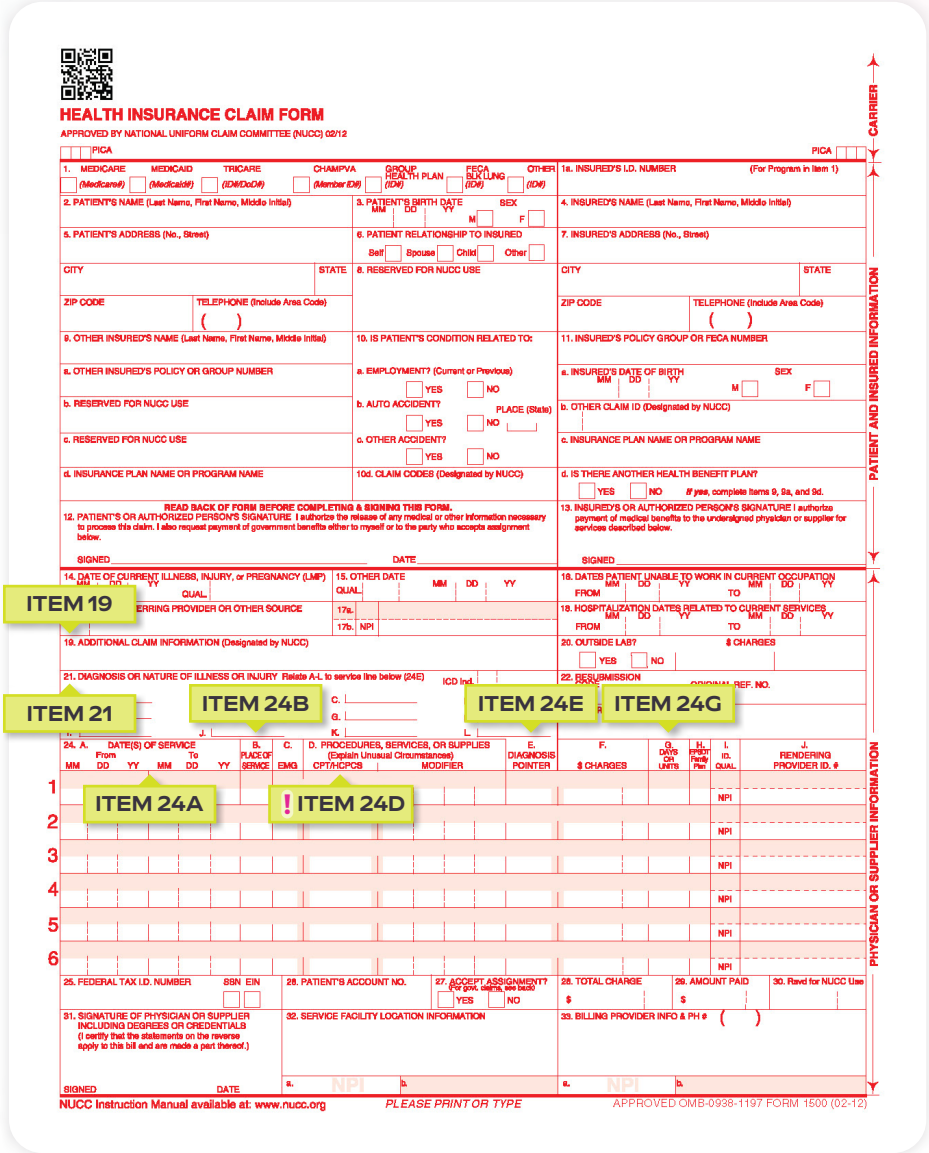
ITEM 24B Enter the appropriate place of service code(s).[16]

ITEM 24D Enter the appropriate CPT (96413) and HCPCS level II code (J9264) and modifiers for procedures, services, and supplies. Additionally, CMS and most payers require you to record drug wastage by including a **JZ modifier** denoting zero waste (ie, J9264-JZ) or a **JW modifier** denoting drug waste (ie, J9264-JW). The amount of drug wastage should be reported on a separate claim line.[11,16]

ITEM 24E Enter the diagnosis code reference number or letter (as appropriate, per form version) as shown in Item 21 to relate the date of service and the procedures performed to the primary diagnosis. Enter only 1 reference number/letter per line item. If multiple services were performed, enter the primary reference number/letter for each service.[16]

ITEM 24G Enter the number of units of nab-paclitaxel administered. 1 mg=1 billing unit.[16,17]

CMS-1500*



CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*; NDC, National Drug Code.

*CMS 837P (not shown) is the electronic equivalent of CMS-1500 and should be used if you submit your claims electronically.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

Completing a CMS-1450 (UB-04) Form for nab-paclitaxel Reimbursement

The UB-04 form is used when billing hospital outpatient claims. The sample annotated form below provides guidance on completing a UB-04 by populating fields that health plans require for nab-paclitaxel reimbursement.

Please confirm the accuracy of the codes you use to bill for nab-paclitaxel with each payer. If submitting to a MAC, refer to the specific MAC's guidelines for completion of the reimbursement forms. **This sample claim form is intended for use only as a reference. The codes provided are subject to change and should not be construed as legal or billing advice.**

Form Locator (FL) 42 Enter a 4-digit revenue code that best describes the services provided, in accordance with hospital billing policy (and that explains each charge documented in FL 47). When listing more than one revenue code, list the codes in ascending order. CMS recommends using revenue code 0636 (drugs requiring detailed coding).[12,18] **Refer to page 8 for a list of potential revenue codes.**

FL 43 Provide a narrative description or standard abbreviation for each revenue code shown in FL 42 on the adjacent line in FL 43. If an NDC is required, submit "N4" followed by the 11-digit NDC, UN, and the number of units administered (eg, N4XXXXX0XXXXXUN100).[18]

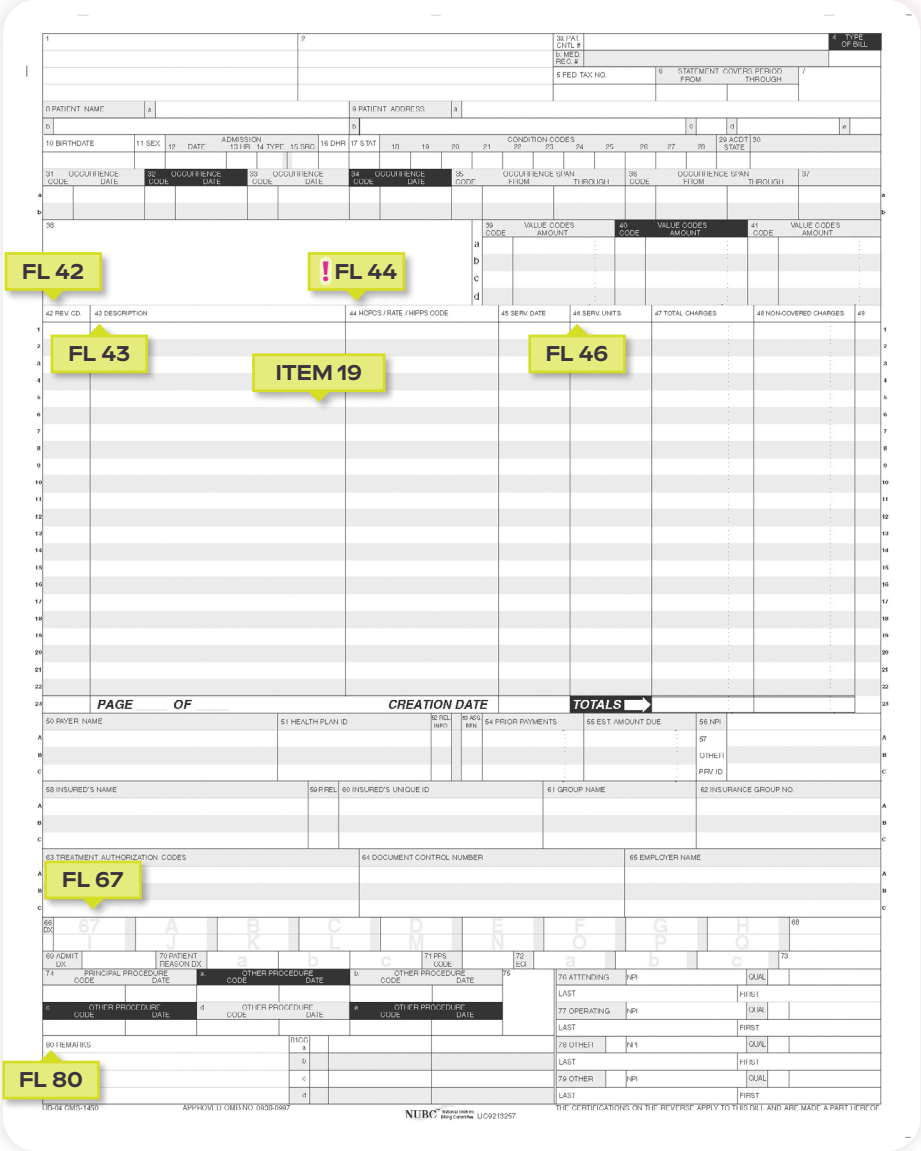
FL 44 Enter the HCPCS code, J9264, and the CPT code for nab-paclitaxel injection, 96413. CMS and most payers require you to record drug waste. A **JZ modifier** denotes zero waste (ie, J9264-JZ), and a **JW modifier** denotes drug waste (ie, J9264-JW). Drug wastage should be reported on a separate claim line.[11,12,18]

FL 46 Enter the number of units of nab-paclitaxel administered. If drug wastage was reported in FL 44 on a separate claim line with the JW modifier, please indicate the amount of drug wasted here.[11,18]

FL 67 Enter the specific ICD-10-CM diagnosis code(s).[18]

FL 80 Some payers require detailed information about the drug in FL 80. Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement.[12,18]

CMS-1450 (UB-04)*



CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*; MAC, Medicare Administrative Contractor; NDC, National Drug Code; UN, unit.

*CMS 837I (not shown) is the electronic equivalent of CMS-1450/UB-04 and should be used if you submit your claims electronically.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

LIFYORLI (relacorilant) Product Information

How LIFYORLI is supplied[1]

LIFYORLI is available in 2 capsule strengths designed to be used together for the prescribed regimen:

25 mg

Not scaled to actual size.

Oval softgel capsule
Opaque dark brown with "CR25" printed in black on the body of the capsule

100 mg

Not scaled to actual size.

Oblong softgel capsule
Opaque yellow with "CR100" printed in black on the body of the capsule

150 mg	
NDC 76346-550-09	**9-dose supply:** 3 cartons (NDC 76346-550-03),* each containing one blister card with three 150-mg doses
NDC 76346-450-01	**1-dose supply:** 1 blister card containing one 150-mg dose

*NDC 76346-550-03 is a 3-dose supply carton and can be dispensed individually if needed. Each 150-mg dose consists of one 100-mg capsule and two 25-mg capsules.

125 mg	
NDC 76346-525-09	**9-dose supply:** 3 cartons (NDC 76346-525-03),† each containing one blister card with three 125-mg doses
NDC 76346-425-01	**1-dose supply:** 1 blister card containing one 125-mg dose

†NDC 76346-525-03 is a 3-dose supply carton and can be dispensed individually if needed. Each 125-mg dose consists of one 100-mg capsule and one 25-mg capsule.

LIFYORLI storage[1]

- Store and dispense LIFYORLI in the original carton. Store LIFYORLI at 20°C to 25°C (68°F to 77°F)
- Temperature excursions are permitted from 15°C to 30°C (59°F to 86°F)

NDC, National Drug Code.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

Acquiring LIFYORLI (relacorilant) + nab-paclitaxel

LIFYORLI is available in an Oncology Optimized Limited Distribution model*

Specialty distributors

Distributor name	Phone	Fax	Website
BioCareSD	(800) 304-3064	N/A	biocare-us.com
Cardinal Health Specialty Distribution	(855) 855-0708	(877) 274-9897	orderexpress.cardinalhealth.com
Cencora ASD Healthcare	(800) 746-6273	(800) 547-9413	asdhealthcare.com
Cencora Oncology Supply	(800) 633-7555	(800) 248-8205	oncologysupply.com
McKesson Plasma and Biologics	(877) 625-2566	(888) 752-7626	connect.mckesson.com
McKesson Specialty Health	(800) 482-6700	(800) 289-9285	mscs.mckesson.com

Specialty pharmacy network†

Pharmacy name	Phone	Fax	Website
Onco360 (Sina Drug, LLC d/b/a Onco360 Louisville)	(877) 662-6633	(877) 662-6355	onco360.com

*The NCODA-preferred model for oncology care delivery, Oncology Optimized Limited Distribution, excludes PBM-affiliated mail-order pharmacies while allowing medically integrated dispensing pharmacies and non-PBM mail-order pharmacies to dispense. This approach promotes coordinated, in-practice care and ensures timely, patient-centered treatment.[19]
†For US and Puerto Rico.

To access nab-paclitaxel, continue to obtain the infusion medication from your current, preferred distributor.

NCODA, Network for Collaborative Oncology Development & Advancement; PBM, pharmacy benefit manager.

Please see Important Safety Information on pages 15 and 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

LIFYORLI Support and Other Helpful Resources

Lifyorli SUPPORT™

We're here if you need us

LIFYORLI Support can help

Call **1-85-LIFYORLI** (1-855-439-6754), Monday-Friday, 8 AM-8 PM ET

Scan the QR code **for more information and downloadable access resources** to help your patients get started on LIFYORLI: **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.

Please see additional Important Safety Information on page 16 and the accompanying full Prescribing Information.

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions: (cont'd)

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 (≥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 (≥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.

References: 1. LIFYORLI (relacorilant) Prescribing Information. Corcept Therapeutics, Inc. 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.** Colombo N, Botbyl J, Kesner-Hays A, et al. Relacorilant + nab-paclitaxel vs nab-paclitaxel in platinum-resistant ovarian cancer: pharmacokinetics and pharmacokinetic/pharmacodynamic exposure-response. Presented at: European Society of Gynaecological Oncology (ESGO): February 26-28, 2026. **4.** Colombo N, Van Gorp T, Matulonis U, et al. Relacorilant + nab-paclitaxel in patients with recurrent, platinum-resistant ovarian cancer: a three-arm, randomized, controlled, open-label phase II study. *J Clin Oncol*. 2023;41(30):4779-4789. **5.** Supplement to: Olawaiye AB, Gladieff L, O'Malley DM, et al. Relacorilant and nab-paclitaxel in patients with platinum-resistant ovarian cancer (ROSELLA): an open-label, randomized, controlled, phase 3 trial. *Lancet*. 2025;405(10496):2205-2216. **6.** Centers for Medicare & Medicaid Services. ICD-10. Accessed October 30, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes **7.** CPT® 96413, under injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration. Codify by AAPC. Accessed October 30, 2025. https://www .aapc.com/codes/cpt-codes/96413 **8.** CMS Blue Button API. Revenue center code. Accessed December 19, 2025. https://bluebutton.cms.gov/resources/variables/rev_cntr **9.** Centers for Medicare & Medicaid Services. Billing and coding: paclitaxel. Accessed October 30, 2025. https://www .cms.gov/medicare-coverage-database/view/article.aspx?articleId=52450&ver=80 **10.** Centers for Medicare & Medicaid Services. Discarded drugs. Accessed December 20, 2025. https://www .cms.gov/medicare/payment/part-b-drugs/ discarded-drugs **11.** Centers for Medicare & Medicaid Services. Medicare program. Discarded drugs and biologicals—JW modifier and JZ modifier policy frequently asked questions. Accessed October 27, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **12.** Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 17-drugs and biologicals. Updated June 6, 2025. Accessed October 27, 2025. https://www .cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf **13.** X12. CPT04 units for the 837I and 837P. Accessed October 29, 2025. https://x12.org/resources/requests-for-interpretation/rfi-2151-cpt04-units-837i-and-837p **14.** Centers for Medicare & Medicaid Services. Professional claim. Accessed October 27, 2025. https://www .cms.gov /Medicare/Billing/ElectronicBillingEDITrans/downloads/professionalclaim4010a1to5010.pdf **15.** CareSource. HIPAA transaction standard companion guide. CareSource outbound 837 health care claim: professional vendor 5010 companion guide. Accessed October 29, 2025. https://www.caresource.com/documents/837-p-companion-guide-outbound/? **16.** Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 26: completing and processing form CMS-1500 data set. Updated August 9, 2024. Accessed October 29, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **17.** Centers for Medicare & Medicaid Services. Billing and coding guidelines for drugs and biologics (non-chemotherapy). Accessed December 20, 2025. https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/34741_51/L34741_INJ041_BCG.pdf **18.** Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 25: completing and processing the form CMS-1450 data set. Updated December 20, 2023. Accessed October 29, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf **19.** Oncology Optimized Limited Distribution. NCODA.org. Accessed November 10, 2025. https://www.ncoda.org/oold/

LIFYORLI, LIFYORLI Support, and the LIFYORLI logo are trademarks of Corcept.
Corcept and the Corcept logo are registered trademarks.
All other trademarks are the property of their respective owners.
© 2026 Corcept. All rights reserved. US-REL-25-0023 04-26

Corcept THERAPEUTICS

Lifyorli™ (relacorilant) 100 mg, 25 mg capsules