

REIMBURSEMENT RESOURCE GUIDE

ONIVYDE® (irinotecan liposome injection)

- Coverage, Coding, and Payment in the Physician Office
- Coverage, Coding, and Payment in the Hospital Outpatient Department
- IPSEN CARES Overview
- Important Safety Information

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

Hours: 8:00 AM - 8:00 PM ET, Monday - Friday
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Mail: 11800 Weston Parkway Cary, NC 27513
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Please see accompanying full [Prescribing Information](#), including **Boxed Warning**.

 onivyde®
(irinotecan liposome
injection)

This guide is provided for informational purposes only. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and specific billing requirements. Ipsen Biopharmaceuticals, Inc. (Ipsen) does not make any representation or guarantees concerning reimbursement or coverage for any service or item, nor does Ipsen guarantee patient assistance to the limits described.

COVERAGE, CODING, AND PAYMENT IN THE PHYSICIAN OFFICE

ONIVYDE® (irinotecan liposome injection) received FDA approval on October 22, 2015, and is indicated, in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. ONIVYDE is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas. ONIVYDE has a **BOXED WARNING** on the risks of severe neutropenia and severe diarrhea. ONIVYDE is contraindicated in patients who have experienced a severe hypersensitivity reaction to ONIVYDE or irinotecan HCl. Please see Important Safety Information on page 11 of this guide.

COVERAGE

For Medicare patients, ONIVYDE is covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.^a There are no prior authorization requirements for ONIVYDE under traditional fee-for-service Medicare. For patients enrolled in Medicaid, a Medicare Advantage plan, or a commercial health plan, coverage of ONIVYDE will vary by payer. Some payers may also apply utilization restrictions for ONIVYDE.

CODING

Please refer to the table below to support appropriate claims processing for ONIVYDE.^a

Code Type	Code	Code Description
ICD-10-CM ^b	C25.0	Malignant neoplasm of head of pancreas
	C25.1	Malignant neoplasm of body of pancreas
	C25.2	Malignant neoplasm of tail of pancreas
	C25.3	Malignant neoplasm of pancreatic duct
	C25.7	Malignant neoplasm of other parts of pancreas
	C25.8	Malignant neoplasm of overlapping sites of pancreas
	C25.9	Malignant neoplasm of pancreas, unspecified
ICD-10-CM (Secondary Diagnosis Code)	C79.89	Secondary malignant neoplasm of other specified sites
	C79.9	Secondary neoplasm of unspecified site
CPT ^c	96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug (Code covers infusions lasting up to 90 minutes)
HCPCS ^d	J9205	Injection, irinotecan liposome, 1 mg
NDC ^e	15054-0043-01	ONIVYDE single-dose 10 mL vial containing 43 mg of irinotecan liposome for injection

^aIt is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for actual products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies; ^bInternational Classification of Diseases, 10th Revision, Clinical Modification; ^cCurrent Procedural Terminology; ^dHealthcare Common Procedure Coding System; ^eNational Drug Code. CPT ©2020 American Medical Association. All rights reserved.

PAYMENT

Payer Type	Payment Methodology
Medicare	Average Sales Price (ASP) + 6% (Beginning April 1, 2013, Medicare provider payments were cut by 2% due to sequestration. This reduces Medicare payments for drugs to ASP + 4.3% until 2030 or until there is a legislative change.)
Medicaid and Commercial Payers	Most non-Medicare payers are expected to pay separately for ONIVYDE; however, payment rates will vary by payer and provider contract.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

 **onivyde®**
(irinotecan liposome injection)

3 Please see Important Safety Information on page 11 and accompanying full [Prescribing Information](#), including **Boxed Warning**.

JW MODIFIER

Effective January 1, 2017, Medicare required providers to use the JW modifier (drug amount discarded/not administered to any patient) for all claims with unused drugs or biologicals from single-use vials that are appropriately discarded, and to document the discarded drug or biological in the patient’s medical record.

Wastage-reporting requirements for payers other than Medicare may vary—providers should check with their specific plans about policies related to use of the JW modifier.

PHYSICIAN OFFICE: SAMPLE CMS-1500 CLAIM FORM

ONIVYDE and the associated services provided in a physician office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing ONIVYDE is provided below.

The sample claim form provided below is only an example. It is always the provider’s responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

LOCATOR 19:
Reserved for local use. This area may be used to list the drug name.

LOCATOR 21:
Enter the appropriate primary diagnosis code from the patient’s medical record in Locator 21A, and any secondary diagnosis code(s) in Locator 21B-L.

LOCATOR 24 A-B:
Enter the date of service and the appropriate place of service code.

LOCATOR 24D:
Enter the appropriate HCPCS code.
J9205 - Injection, irinotecan liposome, 1 mg

LOCATOR 24E:
Specify the diagnosis, from Locator 21, that relates to the product or procedure listed in Locator 24D.

LOCATOR 24G:
Enter the number of service units for each line item. A single-dose vial (10 mL) contains 43 billable units of J9205.
Use the JW modifier to report discarded units (if applicable) as required by Medicare or other payers.



COVERAGE, CODING, AND PAYMENT IN THE HOSPITAL OUTPATIENT DEPARTMENT

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CODING

Please refer to the table below to support appropriate claims processing for ONIVYDE.^a

Code Type	Code	Code Description
ICD-10-CM ^b (Primary Diagnosis Code)	C25.0	Malignant neoplasm of head of pancreas
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	C25.3	Malignant neoplasm of pancreatic duct
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Revenue	025X	Pharmacy
	0636	Pharmacy, drugs requiring detailed coding
NDC ^e	15054-0043-01	ONIVYDE single-dose 10 mL vial containing 43 mg of irinotecan liposome for injection

^aIt is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for actual products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies; ^bInternational Classification of Diseases, 10th Revision, Clinical Modification; ^cCurrent Procedural Terminology; ^dHealthcare Common Procedure Coding System; ^eNational Drug Code. CPT ©2020 American Medical Association. All rights reserved.

PAYMENT

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Medicaid and Commercial Payers	Most non-Medicare payers are expected to pay separately for ONIVYDE; however, payment rates will vary by payer and provider contract.



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JW MODIFIER

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Wastage-reporting requirements for payers other than Medicare may vary—providers should check with their specific plans about policies related to use of the JW modifier.

HOSPITAL OUTPATIENT: SAMPLE CMS-1450 (UB-04) CLAIM FORM

ONIVYDE and the associated services provided in a hospital outpatient setting are billed on the CMS-1450 claim form or its electronic equivalent. A sample CMS-1450 claim form for billing ONIVYDE is provided below.

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

The image shows a sample CMS-1450 (UB-04) Claim Form. Several fields are highlighted with green callouts:

- LOCATOR 42:** Points to field 42 (REV CD) and field 43 (DESCRIPTION).
- LOCATOR 43:** Points to field 43 (DESCRIPTION).
- LOCATOR 44:** Points to field 44 (HCPCS / RATE / RPPS CODE).
- LOCATOR 45:** Points to field 45 (SERV DATE).
- LOCATOR 46:** Points to field 46 (SERV UNITS).
- LOCATOR 47:** Points to field 47 (TOTAL CHARGES).
- LOCATOR 67:** Points to field 67 (C25.0).
- LOCATOR 67 A-Q:** Points to fields 67A through 67Q (Secondary Diagnosis Codes).

LOCATOR 43:

Enter the corresponding description for the revenue code listed in Locator 42.

LOCATOR 44:

Enter the appropriate HCPCS code.

J9205 - Injection, irinotecan liposome, 1 mg

LOCATOR 45:

Enter the service date.

LOCATOR 46:

Enter the number of service units for each line item. A single-dose vial (10 mL) contains 43 billable units of J9205. Use the JW modifier to report discarded units (if applicable) as required by Medicare or other payers.

LOCATOR 47:

Enter the total charge for each line item.

LOCATOR 67:

Enter the primary diagnosis code.

LOCATOR 67 A-Q:

Enter any secondary diagnosis code(s) listed in the patient's medical record.

LOCATOR 42:
List the appropriate revenue code for the service provided.
For Medicare: 0636 - Pharmacy, drugs requiring detailed coding.
For payers other than Medicare, the revenue code for ONIVYDE may vary; although some private payers and Medicaid plans accept revenue code 0636 in the hospital outpatient setting, others may require revenue code 025X (Pharmacy).

OVERVIEW

IPSEN CARES (Coverage, Access, Reimbursement & Education Support) serves as a central point of contact between patients, caregivers, doctors' offices, insurance companies, and specialty pharmacies.

The IPSEN CARES Patient Access Specialists are fully dedicated to:

- Facilitating patients' access to the Ipsen medications that are important to their care
- Providing information and support for the interactions between offices, the patients, and insurance companies for Ipsen medications



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Monday – Friday



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REIMBURSEMENT ASSISTANCE

- **Benefits Verification**—verifies patients' coverage, restrictions (if applicable), and copayment/coinsurance amounts
- **Prior Authorization (PA)**—provides information on documentation required by payers on PA specifics, and recommendations for next steps based on payer policy
- **Appeals Support**—provides information on the payer-specific processes required to submit a level I or a level II appeal, as well as provides guidance as needed through the process

FINANCIAL SUPPORT

- **Copay Assistance Program**—covers most out-of-pocket costs related to the use of ONIVYDE for eligible^a patients subject to annual limits
- **Patient Assistance Program (PAP)**—determines patients' eligibility^b for PAP and dispenses free product to eligible patients

PRODUCT ACQUISITION

- **Institutions**—ONIVYDE can be acquired from wholesaler
- **Private Practices**
 - Direct (buy-and-bill) acquisition from a select group of specialty distributors
 - Specialty Pharmacy delivery (IPSEN CARES can provide helpful information on selection of the appropriate specialty provider by calling 1-866-435-5677)

PATIENT SUPPORT

- **360° Communication**—conducts calls to both healthcare provider and patient with status updates about patient's IPSEN CARES enrollment, benefits verification results, coverage status, dispense date, etc

HCP ONLINE PORTAL

Ipsen realizes that more work is now being done by computer rather than paper and fax machines. We hope the HCP Online Portal will be a convenient resource for you and your office. The HCP Online Portal is available to:

- View and submit documents
- Find and check status of enrollment forms
- Send messages to the IPSEN CARES team
- Review patient case/copay notes

After you register and create a profile, your profile will be validated within 1 business day. Visit www.ipsencares.com/hcp-resources to learn more.

^aSee page 9 for Copay Assistance Program Patient Eligibility & Terms and Conditions.

^bPatients may be eligible to receive free drug if they are experiencing financial hardship, have no insurance coverage, are US residents, and received a prescription for an on-label use of ONIVYDE, as supported by information provided in the Program application. Eligibility does not guarantee approval for participation in the program. The PAP provides ONIVYDE product only, and does not cover the cost of previously purchased product or medical services.

ONIVYDE[®] (irinotecan liposome injection) COPAY ASSISTANCE PROGRAM



FINANCIAL ASSISTANCE

- Eligible^a patients may receive up to \$20,000 savings during the program year
- Most eligible patients pay no copay (\$0 copay), with a benefit of up to \$20,000 annual maximum benefit



ACCESS SUPPORT

- Easy enrollment online, by fax, or by phone
- Most benefit verifications are turned around within 1 business day

SIMPLE STEPS FOR ENROLLED PATIENTS TO RECEIVE THEIR ONIVYDE ASSISTANCE

- 1** Provider and patient complete enrollment form and send to IPSEN CARES and patient receives treatment with ONIVYDE.
- 2** Provider submits claim to patient's insurance company.
- 3** Provider adds IPSEN CARES as a secondary or tertiary in EMR system. Provider submits claim to Ipsen utilizing EMR submission to Change Healthcare using CPID 26227, the payer name will be displayed as MSH REIMBUR and the patient's unique ID information.
- 4** Electronic claims should be submitted to the patient's primary and secondary insurance and the EMC process will occur in the background. When the claim is electronically submitted to the patient's primary insurance, it will also be sent to secondary/tertiary insurances to be electronically processed for payment.
- 5** IPSEN CARES processes eligible claim payment to patient's provider typically within 7-10 business days via either electronic funds transfer (EFT) or check.

Note: For fax submission of claims, submit the following documents via fax to 888-525-2416: a) completed claim form (CMS-1450 (UB-04) or CMS-1500 Claim Form) and b) Primary EOB showing itemized claim from the patient's private insurance company with the cost for products and services listed separately.

^aSee page 9 for Copay Assistance Program Eligibility & Terms and Conditions.



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FREQUENTLY ASKED QUESTIONS ABOUT THE COPAY ASSISTANCE PROGRAM

Q: HOW WILL IPSEN CARES DETERMINE IF THE PATIENT IS ELIGIBLE⁹ FOR THE COPAY ASSISTANCE PROGRAM?

A: IPSEN CARES will perform a benefits verification to determine if the patient is eligible. If the patient qualifies, he/she will be enrolled in the ONIVYDE Copay Assistance Program.

Q: HOW DOES A PATIENT ENROLL IN THE PROGRAM?

A: Calling IPSEN CARES at 1-866-435-5677 is the first step in the Enrollment Process for the patient.

Q: ARE CASH-PAY PATIENTS STILL ALLOWED TO USE THE PROGRAM?

A: Yes, cash-pay patients may still qualify for the copay program. Eligible cash paying patients will receive up to \$1,666.66 of support per prescription, up to \$20,000 program annual maximum.

Q: HOW DO PATIENTS KNOW THAT THEY HAVE BEEN ENROLLED?

A: The physician may enroll the patient via the online HCP portal or by faxing/mailing the required IPSEN CARES Enrollment Form. Once enrolled, an IPSEN CARES representative will notify patients that they have been enrolled. In addition, patients and their physicians will be mailed letters welcoming them into the program.

Q: HOW DOES THE PHYSICIAN RECEIVE THE PAYMENT?

A: A payment will be made directly to the physician on the patient's behalf. Payments will either be electronic funds transfers (EFTs) or checks.

Q: A PATIENT HAS MULTIPLE EOBs THAT NEED PAYMENT. CAN MULTIPLE EOB SUBMISSIONS BE SENT FOR PAYMENT AT ONE TIME?

A: Yes, multiple EOBs can be submitted at one time, including EOBs 90 days prior to the patient's enrollment date.

⁹**Patient Eligibility & Terms and Conditions:** Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients residing in Massachusetts, Minnesota, Michigan, or Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

Cash-pay patients are eligible to participate. "Cash-pay" patients are defined for purposes of this program as patients without insurance coverage or who have commercial insurance that does not cover ONIVYDE®. Medicare Part D enrollees who are in the prescription drug coverage gap (the "donut hole") are not considered cash-pay patients and are not eligible for copay assistance through IPSEN CARES®. For patients with commercial insurance who are not considered to be cash-pay patients, the maximum copay benefit amount per prescription is an amount equal to the difference between the annual maximum copay benefit of \$20,000 and the total amount of copay benefit provided to the patient in the ONIVYDE® Copay Program. For cash-pay patients, the maximum copay benefit amount per prescription is \$1,666.66, subject to the annual maximum of \$20,000 in total. Patient pays any amount greater than the maximum copay savings amount per prescription.

Patient or guardian is responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or RxCrossroads by McKesson, are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Data related to patient participation may be collected, analyzed, and shared with Ipsen for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary.



OVERVIEW OF IMPORTANT IPSEN CARES FORMS

ENROLLMENT FORM

- Completion and submission of the Enrollment Form is the first step for enrolling in IPSEN CARES/ONIVYDE Copay Assistance Program. The form needs to be printed, filled out completely by the Provider and the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES. The step-by-step instructions ensure that all relevant sections are completed and signed.

PATIENT AUTHORIZATION FORM

- The Patient Authorization Form needs to be completed by the Patient/Legal Guardian in order to maintain participation in IPSEN CARES. The form needs to be printed, filled out completely by the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES. It is important that the Patient/Legal Guardian review the original IPSEN CARES Enrollment Form prior to signing the Authorization Form.

PATIENT ASSISTANCE PROGRAM APPLICATION

- The Patient Assistance Program (PAP) is designed to provide ONIVYDE at no cost to eligible patients. Patients may be eligible to receive free drug if they are experiencing financial hardship, have no insurance coverage, and received a prescription for an on-label use of ONIVYDE, as supported by information provided in the Program application. Eligibility does not guarantee approval for participation in the program. The PAP provides ONIVYDE product only, and does not cover the cost of previously purchased product or medical services. The PAP Application needs to be printed, filled out completely by the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

ONIVYDE® (irinotecan liposome injection) is indicated, in combination with fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Limitation of Use: ONIVYDE is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE NEUTROPENIA and SEVERE DIARRHEA

- **Fatal neutropenic sepsis occurred in 0.8% of patients receiving ONIVYDE. Severe or life-threatening neutropenic fever or sepsis occurred in 3% and severe or life-threatening neutropenia occurred in 20% of patients receiving ONIVYDE in combination with 5-FU and LV. Withhold ONIVYDE for absolute neutrophil count below 1500/mm³ or neutropenic fever. Monitor blood cell counts periodically during treatment**
- **Severe diarrhea occurred in 13% of patients receiving ONIVYDE in combination with 5-FU/LV. Do not administer ONIVYDE to patients with bowel obstruction. Withhold ONIVYDE for diarrhea of Grade 2–4 severity. Administer loperamide for late diarrhea of any severity. Administer atropine, if not contraindicated, for early diarrhea of any severity**

CONTRAINDICATION

- ONIVYDE is contraindicated in patients who have experienced a severe hypersensitivity reaction to ONIVYDE or irinotecan HCl

WARNINGS AND PRECAUTIONS

- **Severe Neutropenia: See Boxed WARNING.** In patients receiving ONIVYDE/5-FU/LV, the incidence of Grade 3/4 neutropenia was higher among Asian (18/33 [55%]) vs White patients (13/73 [18%]). Neutropenic fever/neutropenic sepsis was reported in 6% of Asian vs 1% of White patients
- **Severe Diarrhea: See Boxed WARNING.** Severe and life-threatening late-onset (onset >24 hours after chemotherapy [9%]) and early-onset diarrhea (onset ≤24 hours after chemotherapy [3%], sometimes with other symptoms of cholinergic reaction) were observed
- **Interstitial Lung Disease (ILD):** Irinotecan HCl can cause severe and fatal ILD. Withhold ONIVYDE in patients with new or progressive dyspnea, cough, and fever, pending diagnostic evaluation. Discontinue ONIVYDE in patients with a confirmed diagnosis of ILD
- **Severe Hypersensitivity Reactions:** Irinotecan HCl can cause severe hypersensitivity reactions, including anaphylactic reactions. Permanently discontinue ONIVYDE in patients who experience a severe hypersensitivity reaction

- **Embryo-Fetal Toxicity:** ONIVYDE can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during and for 1 month after ONIVYDE treatment

ADVERSE REACTIONS

- The most common adverse reactions (≥20%) were diarrhea (59%), fatigue/asthenia (56%), vomiting (52%), nausea (51%), decreased appetite (44%), stomatitis (32%), and pyrexia (23%)
- The most common Grade 3/4 adverse reactions (≥10%) were diarrhea (13%), fatigue/asthenia (21%), and vomiting (11%)
- Adverse reactions led to permanent discontinuation of ONIVYDE in 11% of patients receiving ONIVYDE/5-FU/LV; The most frequent adverse reactions resulting in discontinuation of ONIVYDE were diarrhea, vomiting, and sepsis
- Dose reductions of ONIVYDE for adverse reactions occurred in 33% of patients receiving ONIVYDE/5-FU/LV; the most frequent adverse reactions requiring dose reductions were neutropenia, diarrhea, nausea, and anemia
- ONIVYDE was withheld or delayed for adverse reactions in 62% of patients receiving ONIVYDE/5-FU/LV; the most frequent adverse reactions requiring interruption or delays were neutropenia, diarrhea, fatigue, vomiting, and thrombocytopenia
- The most common laboratory abnormalities (≥20%) were anemia (97%), lymphopenia (81%), neutropenia (52%), increased ALT (51%), hypoalbuminemia (43%), thrombocytopenia (41%), hypomagnesemia (35%), hypokalemia (32%), hypocalcemia (32%), hypophosphatemia (29%), and hyponatremia (27%)

DRUG INTERACTIONS

- Avoid the use of strong CYP3A4 inducers, if possible, and substitute non-enzyme inducing therapies ≥2 weeks prior to initiation of ONIVYDE
- Avoid the use of strong CYP3A4 or UGT1A1 inhibitors, if possible, and discontinue strong CYP3A4 inhibitors ≥1 week prior to starting therapy

USE IN SPECIFIC POPULATIONS

- **Pregnancy and Reproductive Potential:** See WARNINGS & PRECAUTIONS. Advise males with female partners of reproductive potential to use condoms during and for 4 months after ONIVYDE treatment
- **Lactation:** Advise nursing women not to breastfeed during and for 1 month after ONIVYDE treatment

Please see full [Prescribing Information](#), including **Boxed WARNING**.

REGIONAL REIMBURSEMENT DIRECTORS ARE AVAILABLE TO EDUCATE HEALTHCARE PROFESSIONALS

- Increase healthcare professionals' knowledge about reimbursement of Ipsen products
- Provide information to help address complex reimbursement issues for healthcare professionals
- Explain IPSEN CARES services and support offerings for patients and healthcare professionals

To learn more about ONIVYDE® (irinotecan liposome injection), visit ONIVYDE.com.

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May 2020 ONV-US-002501

 **onivyde®**
(irinotecan liposome
injection)