REIMBURSEMENT RESOURCES OVERVIEW

ONIVYDE® (irinotecan liposome injection)

- IPSEN CARES® Overview
- Patient Financial Support Services
- Coverage, Coding, and Payment in the Physician Office
- Coverage, Coding, and Payment in the Hospital Outpatient Department
- Provider Readiness: Process and Tips
- IPSEN CARES® Sample Enrollment Form
- Important Safety Information

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

Hours: 8:00 AM - 8:00 PM ET, Monday - Friday
Phone: 1-866-435-5677
FAX: 1-888-525-2416
Mail: 11800 Weston Parkway Cary, NC 27513
www.ipsencares.com

Please click here for the full Prescribing Information, including **Boxed Warning**.

onivyde®
(irinotecan liposome injection)

IPSEN CARES®

OVERVIEW

IPSEN CARES® offers an array of services to help you and your patients access ONIVYDE® (irinotecan liposome injection).

IPSEN CARES® can help by offering:

- Benefit verifications
- Prior authorization (PA) information
- Claims and appeals support
- Financial assistance for eligible patients*

BENEFIT VERIFICATION

We know that coverage for ONIVYDE® will vary by plan and by patient. IPSEN CARES® can help determine patient-specific coverage requirements and cost-share responsibility.

1. Complete the ONIVYDE® IPSEN CARES® Enrollment Form and fax to 1-888-525-2416
2. Within 4 business hours, IPSEN CARES® will fax you the benefits verification results and call to answer any questions.
3. Coordinate patient financial assistance services with IPSEN CARES®, if needed.

PRIOR AUTHORIZATION SUPPORT

When IPSEN CARES® identifies a PA requirement while conducting a benefit verification, we can provide you information about the PA process.

IPSEN CARES® will:

- Research the payer requirements as part of the benefit verification process
- Give you information for submitting the prior authorization

CLAIMS AND APPEALS SUPPORT

IPSEN CARES® can support you in submitting claims for ONIVYDE® by:

- Contacting the payer to confirm the claim submission was processed correctly
- Tracking claims until a decision is rendered and relaying results to you
- Helping your office troubleshoot denied or rejected claims

*Patients must meet specified financial and insurance eligibility criteria to qualify for assistance. Ipsen reserves the right to make eligibility determinations and to modify or discontinue the program at any time.

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IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

PATIENT FINANCIAL SUPPORT SERVICES

IPSEN CARES® offers a number of financial assistance options to qualifying patients.

IPSEN CARES® will work with you and your patient to determine eligibility* for the following:

- Patient assistance program (PAP) for uninsured or functionally uninsured patients†
- $0 copay assistance for commercially insured patients
- Referrals to independent, nonprofit organizations

PATIENT ASSISTANCE PROGRAM ELIGIBILITY CRITERIA

Your patient may qualify for PAP if he/she meets all of the following criteria:

- Patient is prescribed ONIVYDE® for FDA-approved indication
- Uninsured/functionally uninsured
- Meet financial criteria
- US Resident

REFERRALS TO INDEPENDENT FOUNDATIONS

Your patient may be eligible for assistance through an independent, nonprofit organization. Eligibility criteria may vary. IPSEN CARES® will:

- Identify potential foundations
- Provide contact information of the foundation
- Patient or HCP office will need to contact the foundation to enroll the patient

APPLICATION PROCESS FOR FINANCIAL SERVICES

- Complete the IPSEN CARES® ONIVYDE® Enrollment Form and collect acceptable income documentation
- Submit all paperwork to IPSEN CARES® via fax at 1-888-525-2416

*Patients must meet specified financial and insurance eligibility criteria to qualify for assistance. Ipsen reserves the right to make eligibility determinations and to modify or discontinue the program at any time.
†Functionally uninsured patients are those who may be enrolled in a health plan but do not have coverage for ONIVYDE®.

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IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

COVERAGE, CODING, AND PAYMENT IN THE

PHYSICIAN OFFICE

ONIVYDE® (irinotecan liposome injection) received FDA approval on October 22nd, 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.

COVERAGE

For Medicare patients, ONIVYDE® will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.* 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®.*

Code Type	Code	Code Description
ICD-10-CM[a]	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[b†]	96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug[‡]
HCPCS[c]	J9205	Injection, irinotecan liposome, 1 mg (effective for dates of service on or after January 1, 2017)[§]
NDC[d‖]	15054-0043-01[†]	Onivyde® single-dose 10 mL vial containing 43 mg of irinotecan liposome for injection

[a]International Classification of Diseases, 10th Revision, Clinical Modification; [b]Current Procedural Terminology; [c]Healthcare Common Procedure Coding System; [d]National Drug Code.

*It 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.

[†]CPT © 2016 American Medical Association. All rights reserved.

[‡]One-hour code covers infusions lasting 16 to 90 minutes.

[§]For dates of service before January 1, 2017, providers should report ONIVYDE® using J3490 (Unclassified drugs) or J9999 (Not otherwise classified, antineoplastic drugs).

[‖]NDC code new under Ipsen as of October 2017.

PAYMENT

Payer Type	Payment Methodology
Medicare	Average Sales Price (ASP) + 6%**
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.

**Beginning April 1, 2013, Medicare provider payments were cut by 2 percent due to sequestration. This reduces Medicare payments for drugs to ASP + 4.3% until 2021 or until there is a legislative change.

Please click here for the full Prescribing Information, including **Boxed Warning**.

onivyde® (irinotecan liposome injection)

JW MODIFIER

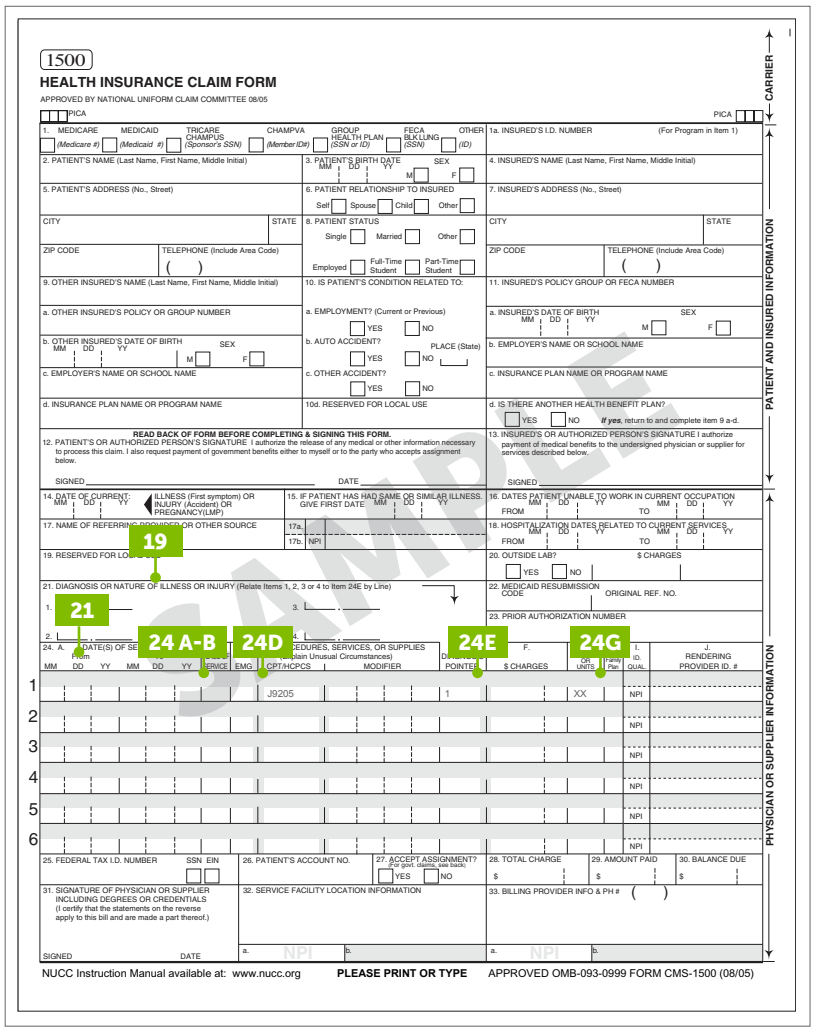
Effective January 1, 2017, Medicare requires providers to use the JW modifier (Drug amount discarded/not administered to any patient) for all claims with unused drugs or biologicals from single use vials that are appropriately discarded, and to document the discarded drug or biological in the patient's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

Please click here for the full Prescribing Information, including **Boxed Warning**.

onivyde® (irinotecan liposome injection)

COVERAGE, CODING, AND PAYMENT IN THE

HOSPITAL OUTPATIENT DEPARTMENT

ONIVYDE® (irinotecan liposome injection) received FDA approval on October 22nd, 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.

COVERAGE

For Medicare patients, ONIVYDE® will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.* 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®*

Code Type	Code	Code Description
ICD-10-CM[a] (Primary Diagnosis Code)	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[bt]	96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug[‡]
HCPCS[c]	J9205	Injection, irinotecan liposome, 1 mg (effective for dates of service on or after January 1, 2017)[§]
Revenue	025X	Pharmacy
	0636	Pharmacy, drugs requiring detailed coding
NDC[d‖]	15054-0043-01[†]	Onivyde® single-dose 10 mL vial containing 43 mg of irinotecan liposome for injection

[a]International Classification of Diseases, 10th Revision, Clinical Modification; [b]Current Procedural Terminology; [c]Healthcare Common Procedure Coding System; [d]National Drug Code.

*It 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.

[†]CPT © 2016 American Medical Association. All rights reserved.

[‡]One-hour code covers infusions lasting 16 to 90 minutes.

[§]For dates of service before January 1, 2017, providers should report ONIVYDE® using J3490 (Unclassified drugs) or J9999 (Not otherwise classified, antineoplastic drugs).

[‖]NDC code new under Ipsen as of October 2017.

PAYMENT

Payer Type	Payment Methodology
Medicare	Average Sales Price (ASP) + 6%**
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.

** Beginning April 1, 2013, Medicare provider payments were cut by 2 percent due to sequestration. This reduces Medicare payments for drugs to ASP + 4.3% until 2021 or until there is a legislative change.

Please click here for the full Prescribing Information, including **Boxed Warning**.

onivyde® (irinotecan liposome injection)

JW MODIFIER

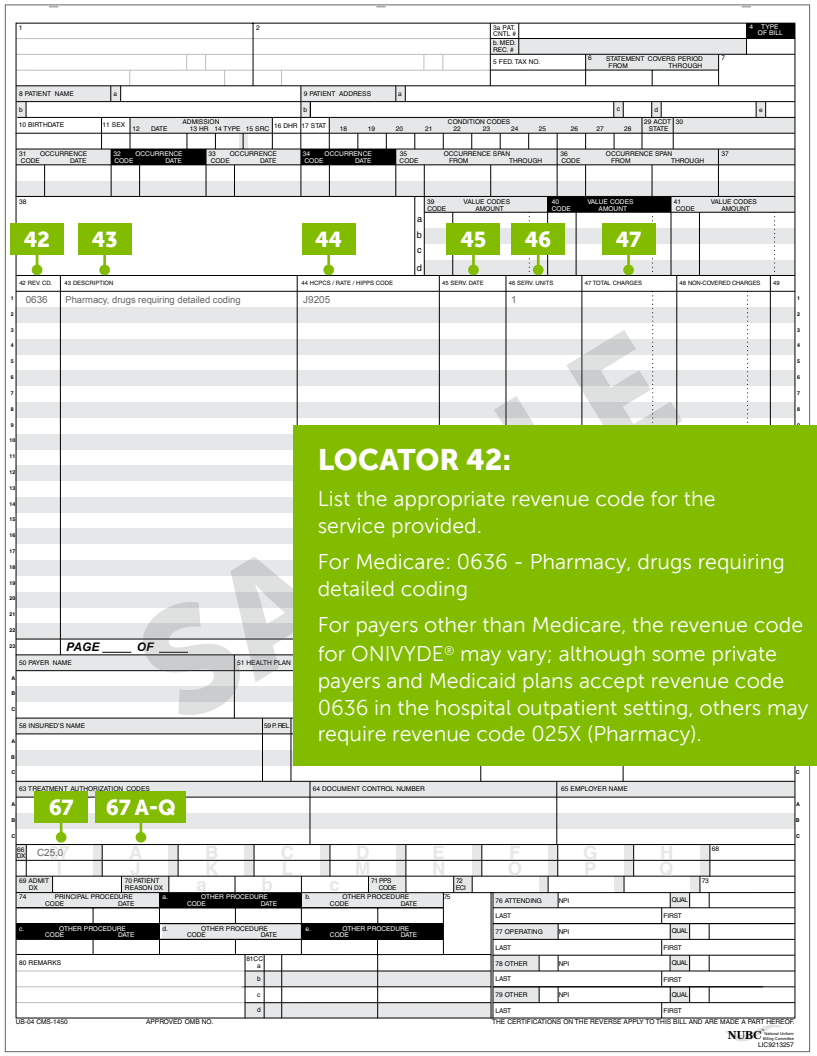
Effective January 1, 2017, Medicare requires providers to use the JW modifier (Drug amount discarded/not administered to any patient) for all claims with unused drugs or biologicals from single use vials that are appropriately discarded, and to document the discarded drug or biological in the patient's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

HOSPITAL OUTPATIENT: SAMPLE UB-04 CLAIM FORM

ONIVYDE® and the associated services provided in a hospital outpatient setting are billed on the UB-04 claim form or its electronic equivalent. A sample UB-04 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 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).

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.

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onivyde® (irinotecan liposome injection)

PROVIDER READINESS: PROCESS

When preparing to treat a patient with ONIVYDE® (irinotecan liposome injection), consider the steps below to facilitate patient access, proper claims submission, and appropriate reimbursement for the drug:

- **Complete the ONIVYDE® IPSEN CARES® Enrollment Form** to initiate a benefit verification and/or eligibility assessment for patient financial assistance, if required
  - Inform IPSEN CARES® if Specialty Pharmacy is preferred, provided it is an option for the patient
  - If a prior authorization (PA) is required, IPSEN CARES® will provide the PA information that will be completed by the HCP office on the patient's behalf.

- If qualified, **enroll the patient in the ONIVYDE® Copay Assistance Program** or provide contact information for the independent non-profit foundations who may be able to assist.
- **Schedule the patient** for his/her ONIVYDE® administration
- **Purchase ONIVYDE®** (if not already in inventory) through one of the following Specialty Distributors: - ASD Healthcare
  - Cardinal Specialty
  - McKesson Plasma and Biologics
  - McKesson Specialty
  - Oncology Supply
- After treatment, **complete and submit the claim to the payer**, including all necessary information and accounting for any unused portion (wastage) of the single-use vial

TO GET STARTED WITH IPSEN CARES®, VISIT WWW.IPSENCARES.COM/ONIVYDE-PATIENT-SUPPORT AND DOWNLOAD THE ENROLLMENT FORM.

Please click here for the full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

PROVIDER READINESS: TIPS

When considering offering ONIVYDE® (irinotecan liposome injection) at your practice, please refer to the steps below to ensure you are prepared for a successful reimbursement experience:

- **Contact commercial payers** and your local Medicare Administrative Contractor (MAC) for additional information about coverage, coding, and reimbursement policies for ONIVYDE®
  - Inquire with commercial payers about the payment methodology for the appropriate unclassified Healthcare Common Procedure Coding System (HCPCS) code
- **Ensure clinical documentation** for each patient is in accordance with payer-specific coverage requirements
- **Know who in your practice is responsible for each of the following tasks:**
  - Verifying patient benefits
  - Securing prior authorizations/pre-certification
  - Discussing cost-share obligations with patients
  - Scheduling appointments for ONIVYDE® administration
  - Purchasing ONIVYDE®
  - Filing claims with payers
- **Update charge master/electronic billing system** to ensure that ONIVYDE® is recognized
- **Anticipate requests from payers** for clinical documentation when filing claims for ONIVYDE®

Please click here for the full Prescribing Information, including **Boxed Warning**.

onivyde® (irinotecan liposome injection)

ENROLLMENT FORM INSTRUCTIONS

TO GET STARTED WITH IPSEN CARES®, VISIT
WWW.IPSENCARES.COM/ONIVYDE-PATIENT-SUPPORT
AND DOWNLOAD THE ENROLLMENT FORM.

WHAT DO I NEED TO FILL OUT?

Complete Pages 1, 2, and 5 of the Enrollment Form for the Following Services:

- All IPSEN CARES® Program Services
- Benefits Verification Only

WHERE DO I SEND THIS FORM?

Fax:
1-888-525-2416

Mail:
IPSEN CARES® Program
11800 Weston Parkway
Cary, NC 27513

WHAT SHOULD I EXPECT NEXT?

IPSEN CARES® Will:

- Acknowledge the Receipt of Your Request
- Initiate the Services You Requested

Please click here for the full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

IPSEN CARES® Enrollment Form

onivyde® (irinotecan liposome injection)

Please print the form, fill it out completely, sign it, and
FAX TO 1-888-525-2416

❑ All IPSEN CARES® Program Services ❑ Benefits Verification Only

PATIENT

Patient Name (First & Last) _____
Patient Address_____
City _____ State _____ Zip ___
Caregiver/Alternate Contact Name _____
Relationship of Caregiver/Alternative Contact to Patient _____
Caregiver/Alternate Contact Phone # (____) _____
Date of Birth (MM/DD/YY) _____/_____ /_____ ❑ Male ❑ Female
Email Address _____
Home Phone # (____) _____ Other Phone # (____) _____
Preferred Language _____

INSURANCE

Complete or attach front and back copy of patient's primary and secondary insurance cards for pharmacy and medical benefits.

Is patient insured? ❑ Yes ❑ No
Does patient have secondary insurance? ❑ Yes ❑ No
Pharmacy Insurance Co. _____
Insurance Co. Phone # (____) _____ Subscriber Policy ID # ____
Policy/Employer/Group # _____
Medical Insurance Co. _____
Insurance Co. Phone # (____) _____
Subscriber Name _____ Policy ID # _____

PRESCRIBER

Prescriber Name_____
DEA # _____ State License # _____
Tax ID #_____ NPI # _____
Medicaid Provider # (Required if Medicaid Patient) _____
Medicare PTAN # (Required if Medicare Patient) _____
Office/Institution _____
Specialty ❑ Oncologist ❑ Endocrinologist ❑ Other _____
Street Address _____
City _____ State _____ Zip _____
Office Contact and Title _____
Phone # (____) _____ Fax # (____) _____
Email Address _____
Preferred Method of Contact ❑ Phone ❑ Fax

PRESCRIPTION

ONIVYDE® (irinotecan liposome) injection

Indication	Strength	Frequency
❑ Metastatic Adenocarcinoma of the Pancreas	❑ 70 mg/m^2 ❑ Other	❑ 2 weeks ❑ Other _____

Quantity _____ Number of Refills _____

Route: Intravenous Injection (IV)

Directions for Use _____

PRESCRIBER/OFFICE MANAGER ATTESTATION

(The Prescriber must sign if this form is to be used as a prescription to be triaged to enroll a patient for free goods as part of the Patient Assistance Program (PAP). The office manager of the Prescriber may sign if the request is limited to Benefit Verification or Copay Assistance Support.)

By signing below, I certify that a prescription signed by a licensed prescriber is on file or provided above for the above therapy and that the patient has provided the necessary authorization to release the above referenced information and medical and/or patient information relating to Onivyde® therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for Onivyde® therapy, assisting in initiating or continuing Onivyde® therapy, and/or evaluating the patient's eligibility for Ipsen's patient support programs administered by IPSEN CARES®. These medications will not be offered for sale, trade, or barter. Additionally, no claim for reimbursement will be submitted concerning these medications to Medicare, Medicaid, or any third party, nor will any medications be returned for credit. If named patient does not return for therapy, product will be returned to Ipsen. I acknowledge that I have assisted the patient in enrolling in IPSEN CARES® exclusively for purposes of patient care and not in consideration for, expectation of, or actual receipt of remuneration of any sort.

For Prescriber Only: I authorize Ipsen to be my agent and to forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen by the above-named patient. For the state of New York, copies of all prescriptions should be on official New York state prescription forms. I certify that any medications received from Ipsen in connection with any IPSEN CARES® program will be used only for the patient named on this form.

Name _____ Title _____
Signature _____ Date _____

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IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

IPSEN CARES®
Enrollment Form (continued)

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.

Have you documented that your patient has experienced an inadequate response to or cannot be treated with surgery and/or radiotherapy?

❑ Yes ❑ No

Diagnosis (ICD-10-CM Code) _____ Description _____

CPT Code _____ Description_____

Date of Diagnosis _____/_____/_____ Therapy Start Date _____/_____/_____

Have other products been used to treat this patient? ❑ Yes ❑ No Product _____ Date of Last Injection _____/_____/_____

Allergies ❑ No Known Drug Allergies ❑ List Allergies _____

List Medications _____

Please see pages 15 and 16 for Important Safety Information and accompanying full Prescribing Information, including **Boxed Warning**.

MAIL OR FAX COMPLETED FORM AND FINANCIAL DOCUMENTATION TO:

Mail: IPSEN CARES® Program
11800 Weston Parkway
Cary, NC 27513

Fax: 1-888-525-2416

CONTACT:

Hours: 8AM–8PM ET, Monday–Friday
Phone: 1-866-435-5677

Please click here for the full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

onivyde® (irinotecan liposome injection)

Please print the form, sign it, and fax it to IPSEN CARES® at **1-888-525-2416**, or send the form to:
IPSEN CARES® Program
Ipsen Biopharmaceuticals, Inc.
11800 Weston Parkway
Cary, NC 27513

PATIENT AUTHORIZATION

Patient Authorization and Signature - IPSEN CARES® Program

I authorize my healthcare providers (including those pharmacies that may receive my prescription for ONIVYDE®), to disclose personal health information (PHI) about me, including health information relating to my medical condition, treatment, and insurance coverage, to Ipsen Biopharmaceuticals, Inc., its affiliates, and its agents that have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (IPSEN CARES®) program on its behalf (collectively, "Ipsen") in order for Ipsen to (1) enroll me in IPSEN CARES®; (2) establish my benefit eligibility and potential out-of-pocket costs for ONIVYDE®; (3) communicate with my healthcare providers and health plans about my treatment plan; (4) provide support services including patient education and financial assistance for ONIVYDE®; (5) help get ONIVYDE® shipped to me or my healthcare providers; (6) evaluate my eligibility for home health administration if requested by my physician; and (7) facilitate my participation in ONIVYDE® patient programs that I have elected to receive information about, as indicated below. I agree that, using the contact information I provide, Ipsen may get in touch with me for reasons related to the IPSEN CARES® program and support services and may leave messages for me that may disclose that I am on ONIVYDE® therapy. I consent to being contacted by an IPSEN CARES® program representative in order for the program to obtain further information or clarification regarding any adverse event I may experience. Similarly, I consent to a program representative contacting my doctor or other healthcare professional for the same purpose.

I understand that once my PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws and Ipsen may re-disclose it; however, Ipsen has agreed to protect my PHI by using and disclosing it only for the purposes described above or as required by law. I understand that my healthcare providers may receive remuneration from Ipsen in exchange for my PHI and/or for any therapy support services provided to me.

I can withdraw this authorization by calling IPSEN CARES® at 1-866-435-5677 or mailing a letter requesting such revocation to IPSEN CARES®, 11800 Weston Parkway, Cary, NC 27513, but it will not change any actions taken before I withdraw authorization. Withdrawal of authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon my authorization. I understand that I may refuse to sign this form and, if I do so, I will not be able to participate in IPSEN CARES® programs, but it will not affect my eligibility to obtain medical treatment, my ability to seek payment for this treatment or affect my insurance enrollment or eligibility for insurance coverage. This authorization expires one year after the date I sign it below. I understand that I will receive a copy of the signed authorization.

Patient Name _____ Caregiver _____
Name _____ Relationship to Patient _____
Signature _____ Date _____
Patient Date of Birth _____ Patient Phone Number _____

ADDITIONAL PRODUCT AND SUPPORT INFORMATION

In addition to participating in the IPSEN CARES® program, I would also like to receive information from Ipsen, which may include marketing and educational material about ONIVYDE® and programs that support patients. I understand that I do not have to sign this section of the form in order to participate in the IPSEN CARES® program and that I may revoke my authorization to receive additional product information at any time. By signing below, I agree that Ipsen and its agents may use and disclose my personal information (including name, address, phone number, and/or email of the parent/caregiver) to provide these services and Ipsen may also contact me to solicit my opinions regarding ONIVYDE® and Ipsen's products and services. I understand that my cell phone carrier's standard rates may apply for calls to my cell phone. This authorization is valid for one year from the date I sign the form. I may revoke this authorization, by calling 866.435.5677 or sending a request in writing to: IPSEN CARES®, 11800 Weston Parkway, Cary, NC 27513.

Patient Name _____ Caregiver _____
Name _____ Relationship to Patient _____
Signature _____ Date _____

Please click here for the full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

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.

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/mm^3 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

ONIVYDE can cause severe or life-threatening neutropenia and fatal neutropenic sepsis. In a clinical study, the incidence of fatal neutropenic sepsis was 0.8% among patients receiving ONIVYDE, occurring in 1/117 patients in the ONIVYDE + 5-FU/LV arm and 1/147 patients receiving ONIVYDE as a single agent. Severe or life-threatening neutropenia occurred in 20% of patients receiving ONIVYDE + 5-FU/LV vs 2% of patients receiving 5-FU/LV. Grade 3/4 neutropenic fever/neutropenic sepsis occurred in 3% of patients receiving ONIVYDE + 5-FU/LV, and did not occur in patients receiving 5-FU/LV. 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

ONIVYDE can cause severe and life-threatening diarrhea. Do not administer ONIVYDE to patients with bowel obstruction. Severe and life-threatening late-onset (onset >24 hours after chemotherapy) and early-onset diarrhea (onset ≤24 hours after chemotherapy, sometimes with other symptoms of cholinergic reaction) were observed. An individual patient may experience both early- and late-onset diarrhea.

In a clinical study, Grade 3/4 diarrhea occurred in 13% of patients receiving ONIVYDE + 5-FU/LV vs 4% receiving 5-FU/LV. Grade 3/4 late-onset diarrhea occurred in 9% of patients receiving ONIVYDE + 5-FU/LV vs 4% in patients receiving 5-FU/LV; the incidences of early-onset diarrhea were 3% and no Grade 3/4 incidences, respectively. Of patients receiving ONIVYDE + 5-FU/LV, 34% received loperamide for late-onset diarrhea and 26% received atropine for early-onset diarrhea.

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

Based on animal data with irinotecan HCl and the mechanism of action of ONIVYDE, ONIVYDE can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during and for 1 month after ONIVYDE treatment.

ADVERSE REACTIONS

- The most common (≥20%) adverse reactions in which patients receiving ONIVYDE + 5-FU/LV experienced a ≥5% higher incidence of any Grade vs the 5-FU/LV arm, were diarrhea (any 59%, 26%; severe 13%, 4%) (early diarrhea [any 30%, 15%; severe 3%, 0%], late diarrhea

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onivyde® (irinotecan liposome injection)

IMPORTANT SAFETY INFORMATION (CONT'D)

[any 43%, 17%; severe 9%, 4%]), fatigue/asthenia (any 56%, 43%; severe 21%, 10%), vomiting (any 52%, 26%; severe 11%, 3%), nausea (any 51%, 34%; severe 8%, 4%), decreased appetite (any 44%, 32%; severe 4%, 2%), stomatitis (any 32%, 12%; severe 4%, 1%), pyrexia (any 23%, 11%; severe 2%, 1%).

- Of less common (<20%) adverse reactions, patients receiving ONIVYDE (irinotecan liposome injection) + 5-FU/LV who experienced Grade 3/4 adverse reactions at a ≥2% higher incidence of Grade 3/4 toxicity vs the 5-FU/LV arm, respectively, were sepsis (3%, 1%), neutropenic fever/neutropenic sepsis (3%, 0%), gastroenteritis (3%, 0%), intravenous catheter-related infection (3%, 0%), weight loss (2%, 0%), and dehydration (4%, 2%).
- The laboratory abnormalities in which patients receiving ONIVYDE + 5-FU/LV experienced a ≥5% higher incidence vs the 5-FU/LV arm, were anemia (any 97%, 86%; severe 6%, 5%), lymphopenia (any 81%, 75%; severe 27%, 17%), neutropenia (any 52%, 6%; severe 20%, 2%), thrombocytopenia (any 41%, 33%; severe 2%, 0%), increased alanine aminotransferase (any 51%, 37%; severe 6%, 1%), hypoalbuminemia (any 43%, 30%; severe 2%, 0%), hypomagnesemia (any 35%, 21%; severe 0%, 0%), hypokalemia (any 32%, 19%; severe 2%, 2%), hypocalcemia (any 32%, 20%; severe 1%, 0%), hypophosphatemia (any 29%, 18%; severe 4%, 1%), hyponatremia (any 27%, 12%; severe 5%, 3%), increased creatinine (any 18%, 13%; severe 0%, 0%).
- ONIVYDE can cause cholinergic reactions manifesting as rhinitis, increased salivation, flushing, bradycardia, miosis, lacrimation, diaphoresis, and intestinal hyperperistalsis with abdominal cramping and early-onset diarrhea. Grade 1/2 cholinergic symptoms other than early diarrhea occurred in 12 (4.5%) ONIVYDE-treated patients.
- Infusion reactions, consisting of rash, urticaria, periorbital edema, or pruritus, occurring on the day of ONIVYDE administration were reported in 3% of patients receiving ONIVYDE or ONIVYDE + 5-FU/LV.
- The most common serious adverse reactions (≥2%) of ONIVYDE were diarrhea, vomiting, neutropenic fever or neutropenic sepsis, nausea, pyrexia, sepsis, dehydration, septic shock, pneumonia, acute renal failure, and thrombocytopenia.

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
Advise pregnant women of the potential risk to a fetus. Advise males with female partners of reproductive potential to use effective contraception during and for 4 months after ONIVYDE treatment.

Lactation
Advise nursing women not to breastfeed during and for 1 month after ONIVYDE treatment.

Pediatric
Safety and effectiveness of ONIVYDE have not been established in pediatric patients.

DOSAGE AND ADMINISTRATION

The recommended dose of ONIVYDE is 70 mg/m^2 intravenous (IV) infusion over 90 minutes every 2 weeks, administered prior to LV and 5-FU. The recommended starting dose of ONIVYDE in patients known to be homozygous for the UGT1A1*28 allele is 50 mg/m^2 administered by IV infusion over 90 minutes. There is no recommended dose of ONIVYDE for patients with serum bilirubin above the upper limit of normal. Premedicate with a corticosteroid and an anti-emetic 30 minutes prior to ONIVYDE. Withhold ONIVYDE for Grade 3/4 adverse reactions. Resume ONIVYDE with reduced dose once adverse reaction recovered to ≤Grade 1. Discontinue ONIVYDE in patients who experience a severe hypersensitivity reaction and in patients with a confirmed diagnosis of ILD.
Do not substitute ONIVYDE for other drugs containing irinotecan HCl.

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