Reimbursement Resource Guide

ONIVYDE® (IRINOTECAN LIPOSOME INJECTION)

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

IPSENCARES®
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
www.ipsencares.com

Please see Indication and Important Safety Information on page 3 and 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.

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/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 or anaphylaxis 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 including ONIVYDE 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 7 months after the last dose of 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%)
- The following adverse reactions have been identified during post approval use of ONIVYDE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

  Immune system disorders: Hypersensitivity (including Anaphylactic reaction and Angioedema)

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 the last dose of ONIVYDE treatment
- **Lactation:** Advise nursing women not to breastfeed during and for 1 month after the last dose of ONIVYDE treatment

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including **Boxed WARNING**.

Please see accompanying full Prescribing Information, including **Boxed Warning**.

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 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 3 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

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

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

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

Coverage, Coding, and Payment in the Physician Office (Continued)

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.

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.

JZ Modifier

Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.

Medicare Medically Unlikely Edits (MUEs)

Centers for Medicare and Medicaid Services (CMS) developed MUEs to reduce the paid claims error rate for Part B claims. A MUE for a HCPCS/CPT code is the maximum units of service that a provider would report under most circumstances for a single beneficiary on a single date of service. Not all HCPCS/CPT codes have a MUE.

ONIVYDE has a MUE of 120 billing units.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

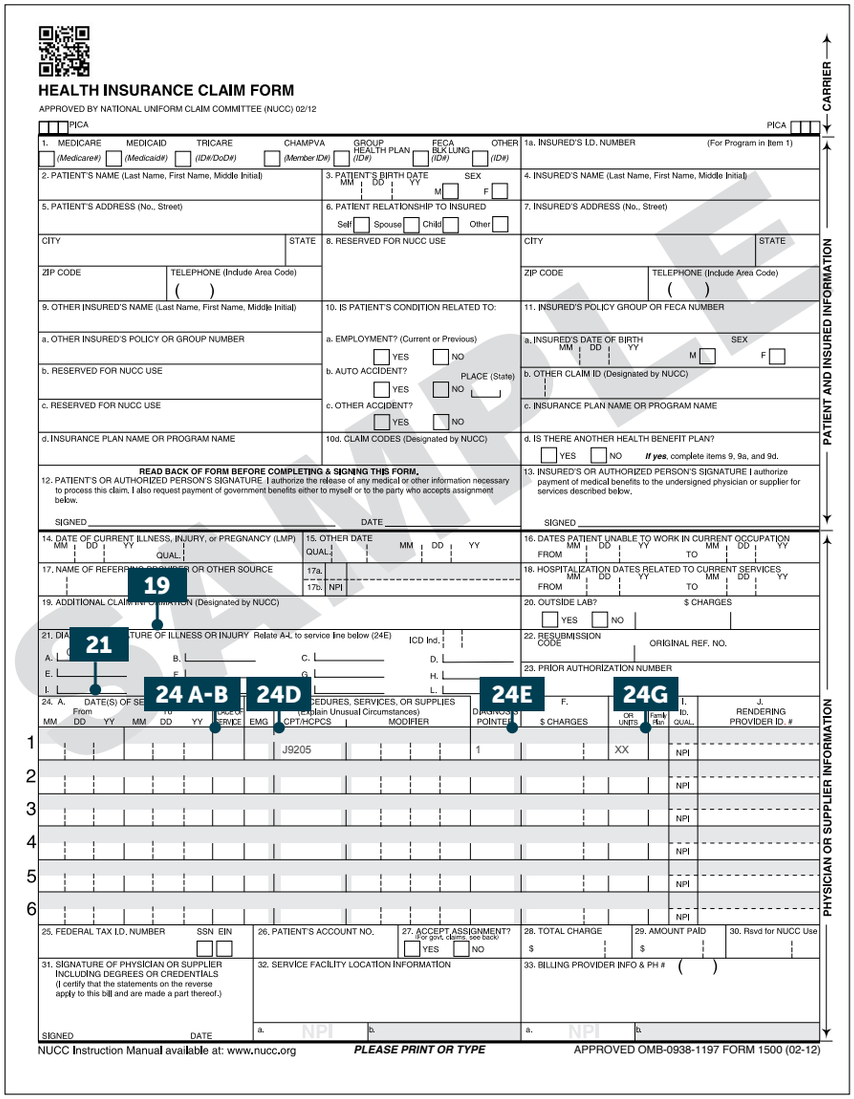
- **Severe Neutropenia: See Boxed WARNING**. In patients receiving ONIVYDE/5-FU/LV, the incidence of Grade 3/4 neutropenia was higher among Asian (18/33 [55%]) vs White patients (13/73 [18%]). Neutropenic fever/neutropenic sepsis was reported in 6% of Asian vs 1% of White patients
- **Severe Diarrhea: 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 including ONIVYDE 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 7 months after the last dose of ONIVYDE treatment

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

Sample CMS-1500 Claim Form
Physician Office

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.

IMPORTANT SAFETY INFORMATION (continued)

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

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSENCARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

Coverage, Coding, and Payment in the Hospital Outpatient Setting

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 3 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] (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[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
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

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

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS (continued)

- 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%)

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

Coverage, Coding, and Payment in the Hospital Outpatient Setting (Continued)

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 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.

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.

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS (continued)

- The following adverse reactions have been identified during post approval use of ONIVYDE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

  Immune system disorders: Hypersensitivity (including Anaphylactic reaction and Angioedema)

DRUG INTERACTIONS

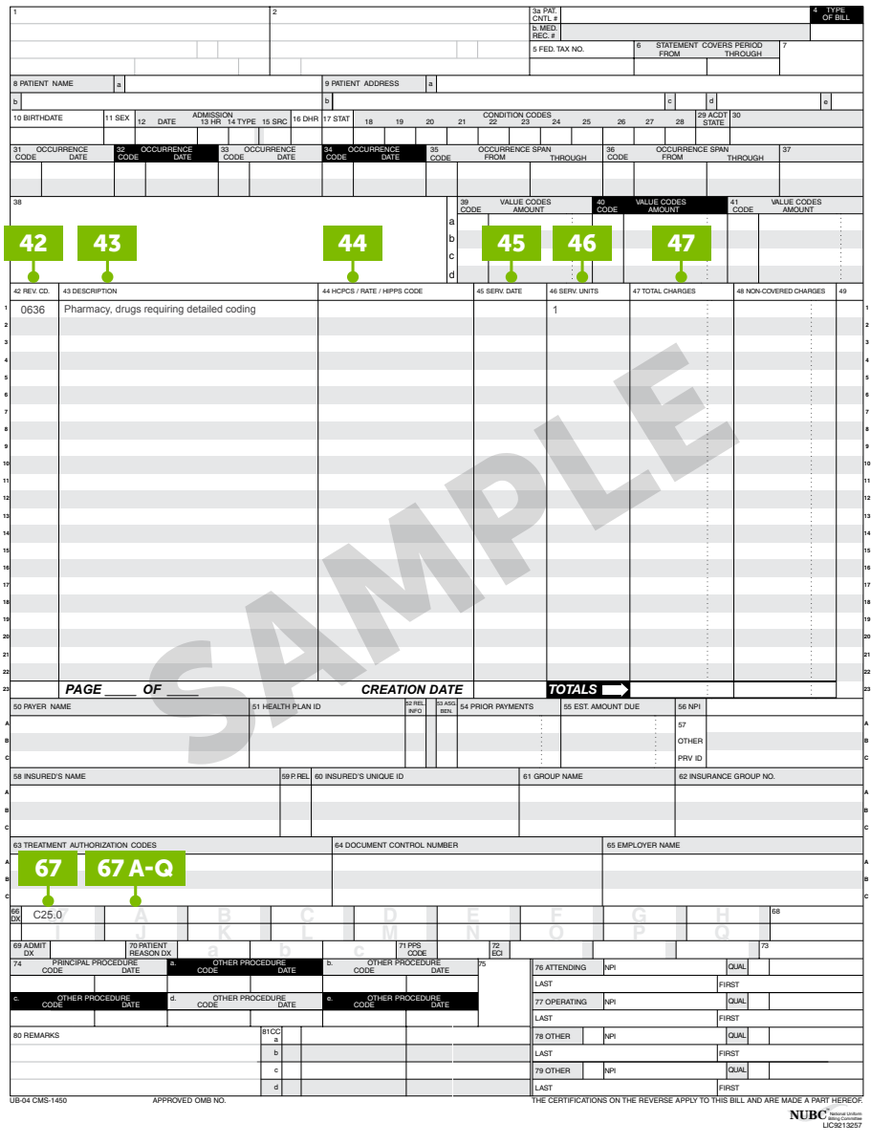
- Avoid the use of strong CYP3A4 inducers, if possible, and substitute non-enzyme inducing therapies ≥2 weeks prior to initiation of ONIVYDE
- Avoid the use of strong CYP3A4 or UGT1A1 inhibitors, if possible, and discontinue strong CYP3A4 inhibitors ≥1 week prior to starting therapy

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

Sample CMS-1450 Claim Form Hospital Outpatient Setting

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.



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.

IMPORTANT SAFETY INFORMATION (continued)

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 the last dose of ONIVYDE treatment
- **Lactation:** Advise nursing women not to breastfeed during and for 1 month after the last dose of ONIVYDE treatment

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

IPSEN CARES Overview

Helping Patients Get Access to Their Prescribed Medications With the Information They Need

IPSEN CARES serves as a central point of contact between patients/caregivers, healthcare providers, insurance companies, and Specialty Pharmacies

The IPSEN CARES Program is staffed by dedicated Patient Support Specialists who can assist in a variety of ways

Phone: 1-866-435-5677
Fax: 1-888-525-2416

Hours: 8:00 am – 8:00 pm ET
Monday – Friday

Website:
www.ipsencares.com

Reimbursement Assistance

- **Benefits Verification** — verifies patients' coverage, restrictions (if applicable), and copayment/coinsurance amounts
- **Prior Authorization (PA)/Appeals**
  - Provides information on documentation required by payers on PA specifics and recommendations for next steps based on payer policy
  - Provides information on the payer appeals process
- **Billing and Coding Information**

Financial Support

- **Copayment Assistance** — offers copayment assistance to eligible[a] patients. This includes referring to the ONIVYDE Commercial Copay Program or referring to an independent non-profit organization, if available
- **Patient Assistance Program (PAP)** — determines patients' eligibility[b] for PAP and dispenses free product to eligible patients

Product Distribution

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

Patient Support

- Communication with providers and patients — 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.
- Medication Reminder Program
  - Patients can opt-in to receive text messages to provide them with reminders on taking their prescribed medication

HCP Portal

The HCP portal saves time and simplifies the interactions with IPSEN CARES on behalf of patients. The HCP portal allows you to track the status of your patients enrolled in IPSEN CARES.

We hope this online portal will be a convenient resource for you and your office. After you register and create a profile, your profile will be validated within 1 business day.

Through the online portal you can:

1. Send a message to the IPSEN CARES team
2. Upload relevant patient documents
3. Obtain Specialty Pharmacy dispensing information (if applicable)
4. Review case status notes for enrolled patients

Visit www.ipsencares.com/hcp-resources to learn more.

[a]See page 12 for Copay Assistance Program Patient Eligibility & Terms and Conditions.

[b]Patients may be eligible for free medication through our PAP. Patients may be eligible to receive free drug if they 1) are experiencing financial hardship, 2) are uninsured or functionally uninsured, 3) are US residents, 4) received a prescription for an on-label use of an Ipsen medication as supported by information provided in the program application, and 5) meet income criteria based on Experian soft credit check. 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.

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

IPSEN CARES Overview

ONIVYDE Copay Assistance Program

FINANCIAL ASSISTANCE	Eligible[a] patients can pay as little as **$0** per prescription
ACCESS SUPPORT	Easy enrollment online, by fax, or by mail

Simple Steps for Patients to Receive Their ONIVYDE Assistance

1. Provider and patient complete and submit enrollment form and send to IPSEN CARES.
2. Patient copay benefit confirmed by IPSEN CARES.
3. Patient is administered ONIVYDE.
4. Provider submits claim to patient's insurance company.
5. Once claim is paid, provider submits the following documents via fax (253-395-8028)
   - Completed CMS-1500 or CMS-1450 form
   - Explanation of benefits (EOB)/remittance from the patient's primary private insurance showing itemized allowed charges and remaining cost share for the ONIVYDE therapy
   - Both Documents must be submitted at the same time to be considered for reimbursement
6. IPSEN CARES processes eligible claim payment to patient's provider typically within 14 business days via either ACH (wire transfer) or check.

[a]See page 12 for Copay Assistance Program Eligibility & Terms and Conditions.

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

IPSEN CARES Overview

Copay Assistance Program

Patient Eligibility & Terms and Conditions: 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, 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.

For patients with commercial insurance, 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.

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 its agents, 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.

ONIVYDE Copay Assistance Program

Frequently Asked Questions

Q: How will IPSEN CARES determine if the patient is eligible[a] 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: Completion and submission of the Enrollment Form is the first step for enrolling in IPSEN CARES. The form can be completed online or 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.

Q: How do patients know that they have been enrolled?

A: 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 be via either ACH (wire transfer) or check.

Q: A patient has multiple Explanation of Benefits (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.

[a]See page 12 for Copay Assistance Program Eligibility & Terms and Conditions.

For additional information about the ONIVYDE Program, call:

1-866-435-5677

Monday – Friday, 8:00 AM – 8:00 PM ET

For additional information, visit us online at www.ipsencares.com

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

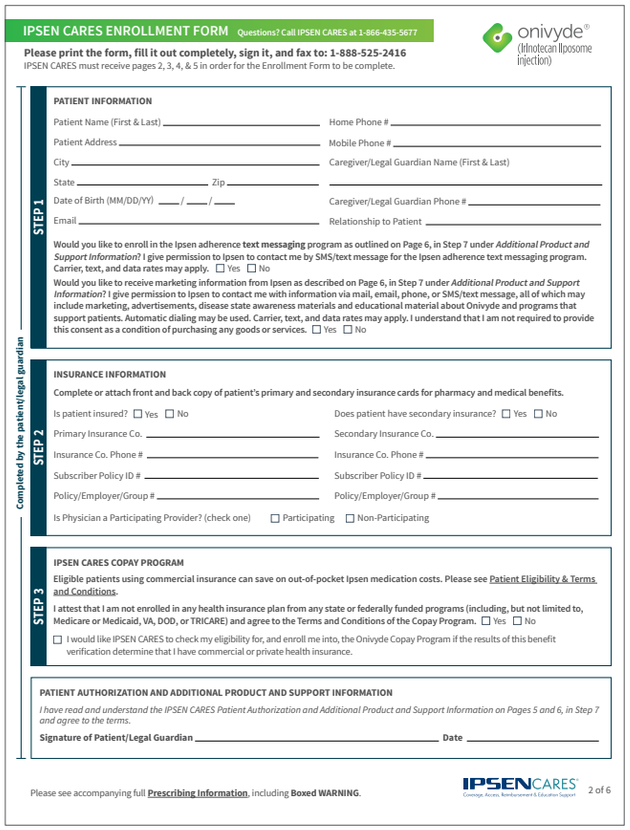
IPSENCARES®
Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

Overview of Important IPSEN CARES Forms

Enrollment Form

Completion and submission of the Enrollment Form is the first step for enrolling in IPSEN CARES. The form can be completed online (at www.IpsenCares.com) or 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.



IPSEN CARES ENROLLMENT FORM Questions? Call IPSEN CARES at 1-866-435-5677

onivyde® (irinotecan liposome injection)

Please print the form, fill it out completely, sign it, and fax to: 1-888-525-2416
IPSEN CARES must receive pages 2, 3, 4, & 5 in order for the Enrollment Form to be complete.

Completed by the patient/legal guardian

STEP 1

PATIENT INFORMATION

Patient Name (First & Last) _____ Home Phone # _____
Patient Address _____ Mobile Phone # _____
City _____ Caregiver/Legal Guardian Name (First & Last)
State _____ Zip _____ _____
Date of Birth (MM/DD/YY) ___/___/___ Caregiver/Legal Guardian Phone # _____
Email _____ Relationship to Patient _____

Would you like to enroll in the Ipsen adherence **text messaging** program as outlined on Page 6, in Step 7 under *Additional Product and Support Information*? I give permission to Ipsen to contact me by SMS/text message for the Ipsen adherence text messaging program. Carrier, text, and data rates may apply. ☐ Yes ☐ No

Would you like to receive marketing information from Ipsen as described on Page 6, in Step 7 under *Additional Product and Support Information*? I give permission to Ipsen to contact me with information via mail, email, phone, or SMS/text message, all of which may include marketing, advertisements, disease state awareness materials and educational material about Onivyde and programs that support patients. Automatic dialing may be used. Carrier, text, and data rates may apply. I understand that I am not required to provide this consent as a condition of purchasing any goods or services. ☐ Yes ☐ No

STEP 2

INSURANCE INFORMATION

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
Primary Insurance Co. _____ Secondary Insurance Co. _____
Insurance Co. Phone # _____ Insurance Co. Phone # _____
Subscriber Policy ID # _____ Subscriber Policy ID # _____
Policy/Employer/Group # _____ Policy/Employer/Group # _____
Is Physician a Participating Provider? (check one) ☐ Participating ☐ Non-Participating

STEP 3

IPSEN CARES COPAY PROGRAM

Eligible patients using commercial insurance can save on out-of-pocket Ipsen medication costs. Please see Patient Eligibility & Terms and Conditions.

I attest that I am not enrolled in any health insurance plan from any state or federally funded programs (including, but not limited to, Medicare or Medicaid, VA, DOD, or TRICARE) and agree to the Terms and Conditions of the Copay Program. ☐ Yes ☐ No

☐ I would like IPSEN CARES to check my eligibility for, and enroll me into, the Onivyde Copay Program if the results of this benefit verification determine that I have commercial or private health insurance.

PATIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT INFORMATION

I have read and understand the IPSEN CARES Patient Authorization and Additional Product and Support Information on Pages 5 and 6, in Step 7 and agree to the terms.

Signature of Patient/Legal Guardian _____ **Date** _____

Please see accompanying full **Prescribing Information**, including **Boxed WARNING**.

IPSENCARES Coverage, Access, Reimbursement & Education Support 2 of 6

Patient Authorization Form

Once a patient is enrolled in IPSEN CARES, a Patient Authorization Form needs to be completed by the Patient/Legal Guardian every 3 years* 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.

*NOTE: The patient authorization will expire sooner than 3 years where required by state law.

IPSEN CARES PATIENT AUTHORIZATION FORM Questions? Call IPSEN CARES at 1-866-435-5677

onivyde® (irinotecan liposome injection)

Please print the form, fill it out completely, sign it, and fax to: 1-888-525-2416.
IPSEN CARES must receive pages 1 and 2 in order for the form to be complete.

PLEASE BE SURE TO REVIEW ORIGINAL IPSEN CARES ENROLLMENT FORM

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, prescription, 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; and (6) 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 contact 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.

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 three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. I understand that I will receive a copy of the signed authorization.

IPSENCARES Coverage, Access, Reimbursement & Education Support 1 of 2

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSENCARES® Coverage, Access, Reimbursement & Education Support

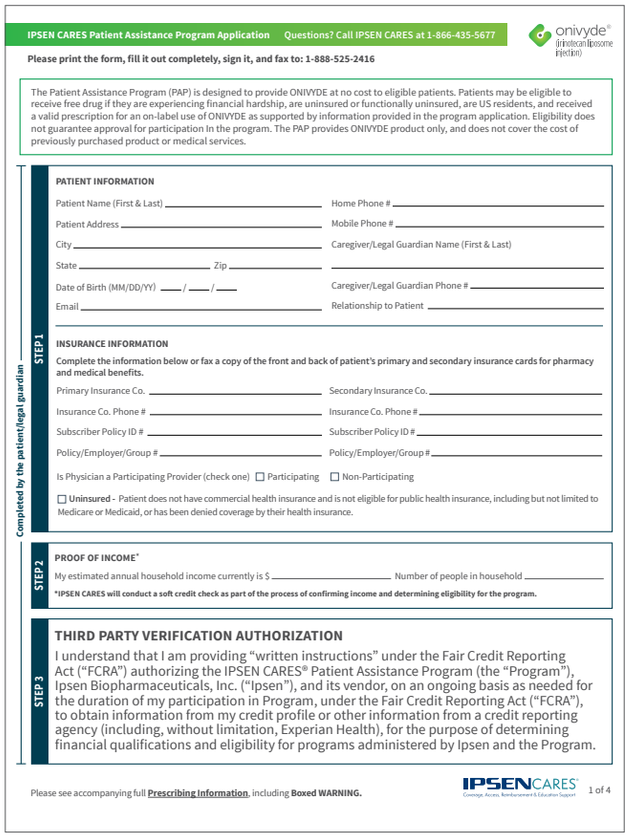
onivyde® (irinotecan liposome injection)

Overview of Important IPSEN CARES Forms (Continued)

Patient Assistance Program (PAP) Application

The Patient Assistance Program (PAP) is designed to provide ONIVYDE at no cost to eligible patients. Patients may be eligible for free medication through our PAP. Patients may be eligible to receive free drug if they 1) are experiencing financial hardship, 2) are uninsured or functionally uninsured, 3) are US residents, 4) received a prescription for an on-label use of an Ipsen medication as supported by information provided in the program application, and 5) meet income criteria based on Experian soft credit check. 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.



IPSEN CARES Patient Assistance Program Application Questions? Call IPSEN CARES at 1-866-435-5677

onivyde® (irinotecan liposome injection)

Please print the form, fill it out completely, sign it, and fax to: 1-888-525-2416

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, are uninsured or functionally uninsured, are US residents, and received a valid 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.

Completed by the patient/legal guardian

STEP 1

PATIENT INFORMATION

Patient Name (First & Last) _____ Home Phone # _____

Patient Address _____ Mobile Phone # _____

City _____ Caregiver/Legal Guardian Name (First & Last)

State _____ Zip _____ _____

Date of Birth (MM/DD/YY) ___ / ___ / ___ Caregiver/Legal Guardian Phone # _____

Email _____ Relationship to Patient _____

INSURANCE INFORMATION

Complete the information below or fax a copy of the front and back of patient's primary and secondary insurance cards for pharmacy and medical benefits.

Primary Insurance Co. _____ Secondary Insurance Co. _____

Insurance Co. Phone # _____ Insurance Co. Phone # _____

Subscriber Policy ID # _____ Subscriber Policy ID # _____

Policy/Employer/Group # _____ Policy/Employer/Group # _____

Is Physician a Participating Provider (check one) ☐ Participating ☐ Non-Participating

☐ **Uninsured** - Patient does not have commercial health insurance and is not eligible for public health insurance, including but not limited to Medicare or Medicaid, or has been denied coverage by their health insurance.

STEP 2

PROOF OF INCOME*

My estimated annual household income currently is $ _____ Number of people in household _____

***IPSEN CARES will conduct a soft credit check as part of the process of confirming income and determining eligibility for the program.**

STEP 3

THIRD PARTY VERIFICATION AUTHORIZATION

I understand that I am providing "written instructions" under the Fair Credit Reporting Act ("FCRA") authorizing the IPSEN CARES® Patient Assistance Program (the "Program"), Ipsen Biopharmaceuticals, Inc. ("Ipsen"), and its vendor, on an ongoing basis as needed for the duration of my participation in Program, under the Fair Credit Reporting Act ("FCRA"), to obtain information from my credit profile or other information from a credit reporting agency (including, without limitation, Experian Health), for the purpose of determining financial qualifications and eligibility for programs administered by Ipsen and the Program.

Please see accompanying full **Prescribing Information**, including **Boxed WARNING.**

IPSENCARES Coverage, Access, Reimbursement & Education Support 1 of 4

Please see Important Safety Information on page 3 and accompanying full Prescribing Information, including **Boxed Warning**.

IPSENCARES® Coverage, Access, Reimbursement & Education Support

onivyde® (irinotecan liposome injection)

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

IPSENCARES®
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
www.ipsencares.com

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

Please see accompanying full Prescribing Information, including **Boxed Warning.**

July 2023 ONV-US-003065 V3.0

onivyde®
(irinotecan liposome injection)