IPSEN CARES® Patient Assistance Program Application

onivyde® (irinotecan liposome injection)

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

The ONIVYDE® 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 ONIVYDE® PAP provides ONIVYDE® (irinotecan liposome injection) product only, and does not cover the cost of previously purchased product or medical services.

Instructions: Both the patient and the healthcare provider have to complete the application.

PATIENT REQUIREMENTS

- Complete and sign the Patient Information section, including the Financial Information section.
- If you are seeking financial assistance from the PAP, please include income information in the below form or the completed Income Statement form included at the end of this application.

HEALTHCARE PROVIDER REQUIREMENTS

- Complete and sign the Healthcare Provider Information section.
- Verify that the patient is being prescribed and administered ONIVYDE®.
- Ensure the entire application is complete and signed before sending it to the fax number provided above.

It is important that you and your healthcare provider complete all requested information and sign where indicated. Since incomplete or incorrect applications will delay the application process, please ensure all information provided is correct.

We recommend that you fax the completed form in order to expedite the process. Once the application is received, we will evaluate the patient's eligibility to participate in the ONIVYDE® PAP. Healthcare providers will be notified upon completion of eligibility review. Please note that program rules are subject to change without notice. For further assistance, please call 1-866-435-5677 from 8:00 AM to 8:00 PM Eastern Time, Monday through Friday.

Please see ONIVYDE® Important Safety Information including **Boxed Warning** on the following pages and accompanying Full Prescribing Information.

Sincerely,

The IPSEN Coverage, Access, Reimbursement & Education Support (CARES®) program

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

Questions? Call IPSEN CARES® at 1-866-435-5677

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PATIENT INFORMATION: THIS SECTION TO BE COMPLETED BY THE PATIENT

First Name _____ MI _____ Last Name _____
Date of birth (MM/DD/YYYY) _____/_____ /_____ Social Security Number _____ Gender ❑ Male ❑ Female
Mailing Address _____ Apt # _____
City _____ State _____ Zip _____
Daytime Phone Number (_____)_____ Evening Phone Number (____) _____
Email Address _____ Are you a US resident? ❑ Yes ❑ No
Prescribing Physician _____ Treating Facility _____

PROOF OF ANNUAL HOUSEHOLD INCOME

My estimated annual household income currently is $ _____
(Please include dollar amount of monthly income from)

$_____ Social Security Disability Income (SSDI) (beginning _____ / _____)
$_____ Supplemental Security Income(SSI)
$_____ Aid from the Department of Public Welfare
$_____ Unemployment Benefits (from _____ / to _____ / _____)
$_____ Workers Compensation Benefits (from _____ / to _____ / _____)
$_____ Dividends, interest, or investment accounts
$_____ Employment (myself and/or my spouse)
$_____ Other (includes assistance from family, friends, charity, or church. Please specify the amount of financial assistance you receive - may include percentage of rent, food, etc.)

Number of People in Household _____

Insurance Type	Status	Status	Please indicate Primary (P) or Secondary (S)
Commercial	❑ Approved ❑ Denied ❑ Waiting for Decision	_____ /_____ /_____	
Medicaid	❑ Approved ❑ Denied ❑ Waiting for Decision	_____ /_____ /_____	
Medicare	❑ Approved ❑ Denied ❑ Waiting for Decision	_____ /_____ /_____	
TriCare	❑ Approved ❑ Denied ❑ Waiting for Decision	_____ /_____ /_____	
Healthcare Exchange	❑ Approved ❑ Denied ❑ Waiting for Decision	_____ /_____ /_____	
Other	❑ Approved ❑ Denied ❑ Waiting for Decision	_____ /_____ /_____	
❑ Uninsured	Patient is not eligible for any public health insurance, which includes Medicare and Medicaid, or has been denied coverage by a third-party payer.		

I authorize my doctor(s) and their staff to disclose my personal information, including information about my insurance, prescription, medical condition, and health ("PHI") to Ipsen Biopharmaceuticals, Inc. and/or its agents or third party vendors ("Ipsen") and the Onivyde® Patient Assistance Program (the "PAP"). I know that the information I provide will be used by the PAP to: (1) decide if I am eligible for assistance; (2) operate the PAP; (3) send me information about the PAP and other programs that might help me pay for my medicines; (4) send my information to other programs that might help me pay for my medicines; (5) ask me for financial, insurance, and/or medical information; and/or (6) share my information as required or permitted by law. I authorize the PAP to use information on this Application and any other information I give to the PAP for these same reasons. I also give Ipsen permission to share my PHI and other information with people and companies that work with the PAP; government agencies, including the Centers for Medicare and Medicaid Services; insurance companies, including Medicare Part D plans; my doctor(s) and other people, or institutions who are involved in my healthcare, such as pharmacies and hospitals; and/or other organizations that might help me pay for my medication. I promise that any information, including financial and insurance information, that I provide to the PAP is complete and true, and unless I have said something different in this application, I have no insurance coverage for this product, which includes Medicaid, Medicare, or any public or private assistance programs or any other form of insurance. If my income or health insurance coverage changes, I will notify IPSEN CARES® at 1-866-435-5677. I understand that Ipsen has the right to contact me directly to confirm receipt of medications. Ipsen may revise, change, or terminate this program at any time. All information that I provide may be used by Ipsen, or any third party working on behalf of Ipsen, in connection with the PAP. 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 can withdraw this authorization by contacting 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 this authorization.

Withdrawal of this 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 this authorization. I understand that I may refuse to sign this form and, if I do so, I will not be able to participate in the PAP, but it will not affect my eligibility to obtain medical treatment, my ability to seek payment for this treatment or my insurance enrollment or eligibility for insurance coverage.

Patient/Legal Guardian Signature _____ Date _____

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HEALTHCARE PROVIDER INFORMATION: THIS SECTION MUST BE COMPLETED BY THE PRESCRIBING PHYSICIAN

Prescriber Name _____ Office Contact and Title _____
DEA # _____ State License _____ Office/Institution _____
Tax ID # _____ NPI # _____Street Address _____
Medicaid Provider _____ City _____
Medicare PTAN # _____Phone (_____) _____ Fax (_____) _____
Office/Institution _____ Email Address _____
❑ Oncologist ❑ Other Email Address_____
Preferred method of contact ❑ Phone ❑ Fax

PRESCRIBER ATTESTATION: By signing below, I certify that a prescription signed by a licensed prescriber is on file 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.

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.

Prescriber Signature _____ Date _____

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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.

CONTRAINDICATIONS

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 lateonset (onset >24 hours after chemotherapy) and earlyonset 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 earlyonset diarrhea were 3% and no Grade 3/4 incidences, espectively. 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.

Please See the Following Pages for additional Important Safety Information and accompanying Full Prescribing Information.

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® (irinotecan liposome injection) + 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 [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® + 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 stablished in pediatric patients.

DOSAGE AND ADMINISTRATION

The recommended dose of ONIVYDE® is 70 mg/m2 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/m2 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.

Please See the Accompanying Full Prescribing Information.

IPSEN CARES®
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Please see Indication and Important Safety Information, including Boxed WARNING, for ONIVYDE® (irinotecan liposome injection). Please see Full Prescribing Information.

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