

# 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

**Mail:** 11800 Weston Parkway, Cary, NC 27513

[www.ipsencares.com](http://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.

**IPSEN**CARES™

Coverage, Access, Reimbursement &amp; Education Support

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



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.

## 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<sup>3</sup> or neutropenic fever. Monitor blood cell counts periodically during treatment**
- **Severe diarrhea occurred in 13% of patients receiving ONIVYDE in combination with 5-FU/LV. Do not administer ONIVYDE to patients with bowel obstruction. Withhold ONIVYDE for diarrhea of Grade 2–4 severity. Administer loperamide for late diarrhea of any severity. Administer atropine, if not contraindicated, for early diarrhea of any severity**

## CONTRAINDICATION

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

## WARNINGS AND PRECAUTIONS

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

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

## ADVERSE REACTIONS

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

## DRUG REACTIONS

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

## USE IN SPECIFIC POPULATIONS

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

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](http://www.fda.gov/medwatch).

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

# 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.<sup>a</sup> 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.<sup>a</sup>

Code Type	Code	Code Description
ICD-10-CM <sup>b</sup>	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 <sup>c</sup>	96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug (Code covers infusions lasting up to 90 minutes)
HCPCS <sup>d</sup>	J9205	Injection, irinotecan liposome, 1 mg
NDC <sup>e</sup>	15054-0043-01	ONIVYDE single-dose 10 mL vial containing 43 mg of irinotecan liposome for injection

<sup>a</sup>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; <sup>b</sup>International Classification of Diseases, 10th Revision, Clinical Modification; <sup>c</sup>Current Procedural Terminology; <sup>d</sup>Healthcare Common Procedure Coding System; <sup>e</sup>National Drug Code. CPT ©2021 American Medical Association. All rights reserved.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATION

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

**IPSEN CARES**<sup>™</sup>

Coverage, Access, Reimbursement & Education Support

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

 **onivyde**<sup>®</sup>  
(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.

## 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 HCl can cause severe hypersensitivity reactions, including anaphylactic reactions. Permanently discontinue ONIVYDE in patients who experience a severe hypersensitivity reaction
- **Embryo-Fetal Toxicity:** ONIVYDE can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during and for 1 month after ONIVYDE treatment

**IPSEN CARES**

Coverage, Access, Reimbursement & Education Support

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

 **onivyde**<sup>®</sup>  
(irinotecan liposome injection)

# 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 ( $\geq 20\%$ ) 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 ( $\geq 10\%$ ) 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

**IPSEN CARES**

Coverage, Access, Reimbursement & Education Support

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



**onivyde**<sup>®</sup>  
(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.<sup>a</sup> 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.<sup>a</sup>

Code Type	Code	Code Description
ICD-10-CM <sup>b</sup> (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 <sup>c</sup>	96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug (Code covers infusions lasting up to 90 minutes)
HCPCS <sup>d</sup>	J9205	Injection, irinotecan liposome, 1 mg
Revenue	025X	Pharmacy
	0636	Pharmacy, drugs requiring detailed coding
NDC <sup>e</sup>	15054-0043-01	ONIVYDE single-dose 10 mL vial containing 43 mg of irinotecan liposome for injection

<sup>a</sup>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; <sup>b</sup>International Classification of Diseases, 10th Revision, Clinical Modification; <sup>c</sup>Current Procedural Terminology; <sup>d</sup>Healthcare Common Procedure Coding System; <sup>e</sup>National Drug Code. CPT ©2021 American Medical Association. All rights reserved.

## 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%)

**IPSEN CARES**

Coverage, Access, Reimbursement & Education Support

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



**onivyde**<sup>®</sup>  
(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)

### DRUG REACTIONS

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

**IPSEN CARES**

Coverage, Access, Reimbursement & Education Support

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

 **onivyde**<sup>®</sup>  
(irinotecan liposome injection)



# 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.

1		2		3a PAT CNTL # b. MED REC #		4 TYPE OF BILL	
5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM		7 THROUGH			
8 PATIENT NAME		9 PATIENT ADDRESS					
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION 13 HR 14 TYPE 15 SRC	
16 DHR		17 STAT		18 19 20 21		22 CONDITION CODES	
23		24		25		26	
27		28		29 ACOT STATE		30	
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE	
35 CODE		36 CODE		37 CODE		38	
39 CODE		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT		42	
43		44		45		46	
47		48		49		50	
51		52		53		54	
55		56		57		58	
59		60		61		62	
63		64		65		66	
67		68		69		70	
71		72		73		74	
75		76		77		78	
79		80		81		82	
83		84		85		86	
87		88		89		90	
91		92		93		94	
95		96		97		98	
99		100		101		102	
103		104		105		106	
107		108		109		110	
111		112		113		114	
115		116		117		118	
119		120		121		122	
123		124		125		126	
127		128		129		130	
131		132		133		134	
135		136		137		138	
139		140		141		142	
143		144		145		146	
147		148		149		150	
151		152		153		154	
155		156		157		158	
159		160		161		162	
163		164		165		166	
167		168		169		170	
171		172		173		174	
175		176		177		178	
179		180		181		182	
183		184		185		186	
187		188		189		190	
191		192		193		194	
195		196		197		198	
199		200		201		202	
203		204		205		206	
207		208		209		210	
211		212		213		214	
215		216		217		218	
219		220		221		222	
223		224		225		226	
227		228		229		230	
231		232		233		234	
235		236		237		238	
239		240		241		242	
243		244		245		246	
247		248		249		250	
251		252		253		254	
255		256		257		258	
259		260		261		262	
263		264		265		266	
267		268		269		270	
271		272		273		274	
275		276		277		278	
279		280		281		282	
283		284		285		286	
287		288		289		290	
291		292		293		294	
295		296		297		298	
299		300		301		302	
303		304		305		306	
307		308		309		310	
311		312		313		314	
315		316		317		318	
319		320		321		322	
323		324		325		326	
327		328		329		330	
331		332		333		334	
335		336		337		338	
339		340		341		342	
343		344		345		346	
347		348		349		350	
351		352		353		354	
355		356		357		358	
359		360		361		362	
363		364		365		366	
367		368		369		370	
371		372		373		374	
375		376		377		378	
379		380		381		382	
383		384		385		386	
387		388		389		390	
391		392		393		394	
395		396		397		398	
399		400		401		402	
403		404		405		406	
407		408		409		410	
411		412		413		414	
415		416		417		418	
419		420		421		422	
423		424		425		426	
427		428		429		430	
431		432		433		434	
435		436		437		438	
439		440		441		442	
443		444		445		446	
447		448		449		450	
451		452		453		454	
455		456		457		458	
459		460		461		462	
463		464		465		466	
467		468		469		470	
471		472		473		474	
475		476		477		478	
479		480		481		482	
483		484		485		486	
487		488		489		490	
491		492		493		494	
495		496		497		498	
499		500		501		502	
503		504		505		506	
507		508		509		510	
511		512		513		514	
515		516		517		518	
519		520		521		522	
523		524		525		526	
527		528		529		530	
531		532		533		534	
535		536		537		538	
539		540		541		542	
543		544		545		546	
547		548		549		550	
551		552		553		554	
555		556		557		558	
559		560		561		562	
563		564		565		566	
567		568		569		570	
571		572		573		574	
575		576		577		578	
579		580		581		582	
583		584		585		586	
587		588		589		590	
591		592		593		594	
595		596		597		598	
599		600		601		602	
603		604		605		606	
607		608		609		610	
611		612		613		614	
615		616		617		618	
619		620		621		622	
623		624		625		626	
627		628		629		630	
631		632		633		634	
635		636		637		638	
639		640		641		642	
643		644		645		646	
647		648		649		650	
651		652		653		654	
655		656		657		658	
659		660		661		662	
663		664		665		666	
667		668		669		670	
671		672		673		674	
675		676		677		678	
679		680		681		682	
683		684		685		686	
687		688		689		690	
691		692		693		694	
695		696		697		698	
699		700		701		702	
703		704		705		706	
707		708		709		710	
711		712		713		714	
715		716		717		718	
719		720		721		722	
723		724		725		726	
727		728		729		730	
731		732		733		734	
735		736		737		738	
739		740		741		742	
743		744		745		746	
747		748		749		750	
751		752		753		754	
755		756		757		758	
759		760		761		762	
763		764		765		766	
767		768		769		770	
771		772		773		774	
775		776		777		778	
779		780		781		782	
783		784		785		786	
787		788		789		790	
791		792		793		794	
795		796		797		798	
799		800		801		802	
803		804		805		806	
807		808		809		810	
811		812		813		814	
815		816		817		818	
819		820		821		822	
823		824		825		826	
827		828		829		830	
831		832		833		834	
835		836		837		838	
839		840		841		842	
843		844		845		846	
847		848		849		850	
851		852		853		854	
855		856		857		858	
859		860		861		862	
863		864		865		866	
867		868		869		870	
871		872		873		874	
875		876		877		878	
879		880		881		882	
883		884		885		886	
887		888		889		890	
891		892		893		894	
895		896		897		898	
899		900		901		902	
903		904		905		906	
907		908		909		910	
911		912		913		914	
915		916		917		918	
919		920		921		922	
923		924		925		926	
927		928		929		930	
931		932		933		934	
935		936		937		938	
939		940		941		942	
943		944		945		946	
947		948		949		950	
951		952		953		954	
955		956		957		958	
959		960		961		962	
963		964		965		966	
967		968		969		970	
971		972		973		974	
975		976		977		978	
979		980		981		982	
983		984		985		986	
987		988		989		990	
991		992		993		994	
995		996		997		998	
999		1000		1001		1002	
1003		1004		1005		1006	
1007		1008		1009		1010	
1011		1012		1013			

# IPSEN CARES Overview

## IPSEN CARES Provides Support for Patients and Providers

The IPSEN CARES Patient Access Specialists are fully dedicated to:

- Facilitating patients' access to their prescribed medications
- Providing information and support for the interactions among offices, patients, and insurance companies for Ipsen medications

IPSEN CARES provides a single point-of-contact dedicated to assisting patients, providers, and staff.



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



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



**Website:**  
[www.ipsencares.com](http://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-specific processes required to submit a level I or a level II appeal, as well as provides guidance as needed through the process.

### Financial Support

- **Copayment Assistance** — offers copayment assistance to eligible<sup>a</sup> 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<sup>b</sup> 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

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

### HCP Online Portal

Ipsen realizes that more work is now being done by computer rather than paper and fax machines. We hope 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:

- Submit enrollments and check their status
- Download additional forms and materials
- Send a message to the IPSEN CARES team
- Obtain Specialty Pharmacy dispensing information (if applicable)

Visit [www.ipsencares.com/hcp-resources](http://www.ipsencares.com/hcp-resources) to learn more.

<sup>a</sup>See page 12 for Copay Assistance Program Patient Eligibility & Terms and Conditions.

<sup>b</sup>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 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.

# IPSEN CARES™

Coverage, Access, Reimbursement & Education Support

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



**onivyde®**  
(irinotecan liposome injection)

# IPSEN CARES Overview

## ONIVYDE Copay Assistance Program

### FINANCIAL ASSISTANCE

- Eligible<sup>a</sup> patients may receive up to **\$20,000** savings during the program year
- Eligible<sup>a</sup> 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 enrollment form and send to IPSEN CARES.
- 2 Patient is administered ONIVYDE.
- 3 Provider submits claim to patient's insurance company.
- 4 Once claim is paid, provider submits the following documents via fax (253-395-8028)
  - a. Completed CMS-1500 or CMS-1450 form
  - b. Explanation of benefits (EOB)/remittance from the patient's primary private insurance showing itemized allowed charges and remaining cost share for the ONIVYDE therapy
- 5 IPSEN CARES processes eligible claim payment to patient's provider typically within 7-10 business days via either ACH (wire transfer) or check.

<sup>a</sup>See page 12 for Copay Assistance Program Eligibility & Terms and Conditions.

**IPSEN CARES**<sup>™</sup>

Coverage, Access, Reimbursement & Education Support

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

 **onivyde**<sup>®</sup>  
(irinotecan liposome injection)

# IPSEN CARES Overview

## Copay Assistance Program

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

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

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

**IPSEN CARES™**

Coverage, Access, Reimbursement & Education Support

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



**onivyde®**  
(irinotecan liposome  
injection)

# ONIVYDE Copay Assistance Program

## Frequently Asked Questions

**Q: How will IPSEN CARES determine if the patient is eligible<sup>a</sup> for the Copay Assistance Program?**

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

**Q: How does a patient enroll in the program?**

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

**Q: Are cash-pay patients still allowed to use the program?**

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

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

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

**Q: How does the physician receive the payment?**

**A:** A payment will be made directly to the physician on the patient's behalf. Payments will 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.

<sup>a</sup>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](http://www.ipsencares.com)

**IPSEN**CARES™

Coverage, Access, Reimbursement & Education Support

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

 **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 needs to be printed, filled out completely by the Provider and the Patient/Legal Guardian, signed, and faxed back to IPSEN CARES.

The step-by-step instructions ensure that all relevant sections are completed and signed.

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

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, and 5 in order for the form to be complete.

**onivyde®**  
(irinotecan liposome injection)

**STEP 1: PATIENT INFORMATION** (Completed by the patient)

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

I give permission to enroll in the Ipsen adherence text messaging program as outlined on Page 5, 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

I give permission to Ipsen to contact me with information via mail, email, phone or SMS/text message, all of which may include telemarketing, 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** (Completed by the patient)

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

**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 4 and 5, in Step 7 and agree to the terms.  
Signature of Patient or Caregiver/Legal Guardian \_\_\_\_\_ Date \_\_\_\_\_

**STEP 3: PRESCRIBER INFORMATION** (Completed by the prescriber)

Prescriber Name \_\_\_\_\_ Street Address \_\_\_\_\_  
DEA # \_\_\_\_\_ State License # \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Tax ID # \_\_\_\_\_ NPI # \_\_\_\_\_ Office Contact and Title \_\_\_\_\_  
Medicaid Provider # (Required if Medicaid Patient) \_\_\_\_\_ Phone # \_\_\_\_\_ Fax # \_\_\_\_\_  
Medicare PTAN # (Required if Medicare Patient) \_\_\_\_\_ Email \_\_\_\_\_  
Office/Institution \_\_\_\_\_ Preferred Method of Contact ☐ Phone ☐ Fax ☐ Email  
Specialty ☐ Oncology ☐ Other \_\_\_\_\_ Best time to contact ☐ Morning ☐ Afternoon ☐ Evening

**STEP 4: PATIENT SUPPORT**  
Would you like us to provide Temporary Patient Assistance if patient is eligible? ☐ Yes ☐ No

Please see accompanying full Prescribing Information, including Boxed WARNING.

**IPSENCARES**  
Coverage, Access, Reimbursement & Education Support

## 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

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.

**onivyde®**  
(irinotecan liposome injection)

**PLEASE BE SURE TO REVIEW ORIGINAL IPSEN CARES ENROLLMENT FORM**

**PATIENT AUTHORIZATION 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; (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 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.

Patient Name (First & Last) \_\_\_\_\_ Legal Guardian (First & Last Name) \_\_\_\_\_  
Patient Date of Birth (mm/dd/yy) \_\_\_\_/\_\_\_\_/\_\_\_\_ Relationship to Patient \_\_\_\_\_  
Phone # \_\_\_\_\_ Signature of Patient or Legal Guardian \_\_\_\_\_ Date \_\_\_\_\_

**IPSENCARES**  
Coverage, Access, Reimbursement & Education Support

**IPSENCARES™**  
Coverage, Access, Reimbursement & Education Support

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

**onivyde®**  
(irinotecan liposome injection)



## INDICATION AND IMPORTANT SAFETY INFORMATION

**COVERAGE, CODING, PAYMENT  
PHYSICIAN OFFICE**

**COVERAGE, CODING, PAYMENT:  
HOSPITAL OUTPATIENT SETTING**

## IPSEN CARES OVERVIEW

## 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

**IPSEN**CARES™

Coverage, Access, Reimbursement & Education Support

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

 **onivyde**®  
(irinotecan liposome  
injection)

**IPSEN**CARES™

Coverage, Access, Reimbursement &amp; 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](http://www.ipsencares.com)

To learn more about ONIVYDE® (irinotecan liposome injection), visit [ONIVYDE.com](http://ONIVYDE.com).

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