

Onivyde® (irinotecan liposome injection) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Onivyde 43 mg/10 mL single-dose vial: 4 vials per 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- All indications: 172 billable units per 14 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient does not have bowel obstruction; **AND**
- Therapy will not be substituted for other drugs containing irinotecan HCl; **AND**

Pancreatic Adenocarcinoma † ‡ ◊ ^{1,2}

- Used in combination with fluorouracil and leucovorin; **AND**
 - Patient has locally advanced or metastatic disease; **AND**
 - Used after disease progression with one of the following:
 - Fluoropyrimidine (5-FU or capecitabine) based therapy with no prior irinotecan; **OR**
 - Gemcitabine-based therapy; **OR**
 - Patient has local or metastatic disease recurrence after resection; **AND**
 - Patient completed primary therapy < 6 months ago; **AND**
 - Patient previously received one of the following:
 - Fluoropyrimidine (5-FU or capecitabine) based therapy that did not include irinotecan; **OR**

- Gemcitabine-based therapy; **OR**
- Patient completed primary therapy \geq 6 months ago; **AND**
 - Used as alternate systemic therapy not previously used

Ampullary Adenocarcinoma ‡²

- Used as subsequent therapy for disease progression; **AND**
- Used in combination with fluorouracil and leucovorin; **AND**
- Patient has pancreatobiliary and mixed type disease with good performance status (i.e., ECOG 0-1, with good biliary drainage and adequate nutritional intake); **AND**
- Patient has previously been treated with one of the following:
 - Gemcitabine-based therapy; **OR**
 - Fluoropyrimidine- (5-FU or capecitabine) based therapy if no prior irinotecan; **OR**
 - Oxaliplatin-based therapy if no prior irinotecan

† FDA Approved Indication(s); ‡ Compendia recommended indication; Ⓢ Orphan Drug

IV. Renewal Criteria¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe diarrhea, severe neutropenia, interstitial lung disease, severe hypersensitivity reactions (including anaphylactic reactions), etc.

V. Dosage/Administration^{1,3}

Indication	Dose
All Indications	Administer 70 mg/m ² intravenously every 14 days <u>Note:</u> Patients homozygous for the UGT1A1*28 allele: Administer 50 mg/m ² every 14 days and may titrate up to 70 mg/m ² as tolerated in subsequent cycles.

VI. Billing Code/Availability Information

HCPCS Code:

- J9205 – Injection, irinotecan liposome, 1 mg: 1 billable unit = 1 mg

NDC:

- Onivyde 43 mg/10 mL single dose vial: 15054-0043-xx

VII. References

1. Onivyde [package insert]. Cambridge, MA; Ipsen Biopharmaceuticals, Inc.; February 2023. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) irinotecan liposomal. National Comprehensive Cancer Network, 2023. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2023.
3. Wang-Gillam A, Li CP, Bodky G, NAPOLI-1 study group. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. Lancet. 2016 Feb 6;387(10018):545-557. Doi: 10.1016/S0140-6736(15)00986-1. Epub 2015 Nov 29.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C24.1	Malignant neoplasm of ampulla of Vater
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the 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
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologics. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC