

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) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

- 172 billable units per 14 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient does not have bowel obstruction; **AND**
- Patient is 18 years of age or older; **AND**
- Patient has not previously received conventional irinotecan therapy; **AND**

Pancreatic Adenocarcinoma †

- Must be used in combination with fluorouracil and leucovorin; **AND**
- Patient has locally advanced, unresectable or metastatic disease; **AND**
- Used after disease progression with one of the following:
 - Fluoropyrimidine (5-FU or capecitabine) based therapy; **OR**
 - Gemcitabine-based therapy

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

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Tumor response with 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 the following: severe diarrhea, severe neutropenia, pulmonary toxicity (interstitial lung disease), severe hypersensitivity reactions, etc.

V. Dosage/Administration

Indication	Dose
Pancreatic Cancer	70 mg/m ² intravenously every 14 days <u>Note:</u> Patients homozygous for UGT1A1*28: 50 mg/m ² every 14 days

VI. Billing Code/Availability Information

Jcode:

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

NDC:

- Onivyde 43 mg/10 mL single dose vial: 69171-0398-xx

VII. References

1. Onivyde [package insert]. Cambridge, MA; Merrimack Pharmaceuticals, Inc.; June 2017. Accessed March 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) irinotecan liposomal. National Comprehensive Cancer Network, 2018. 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 2018.
3. First Coast Service Options, Inc. Local Coverage Determination (LCD): Irinotecan (L33727). Centers for Medicare & Medicaid Services, Inc. Updated on 12/14/2016 with effective date 1/1/2017. Accessed March 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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

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 Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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):

Jurisdiction(s): N	NCD/LCD Document (s): L33727
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33727&bc=gAAAAAAAAAAAAAA==	

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