

## Onivyde® (irinotecan liposome injection) (Intravenous)

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04/2020, 04/2021, 04/2022, 04/2023

### 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 <sup>1</sup>

Coverage is provided in the following conditions:

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

#### Universal Criteria <sup>1</sup>

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

#### Pancreatic Adenocarcinoma † ‡ ◊ <sup>1,2</sup>

- 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 ‡<sup>2</sup>

- 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 Criteria<sup>1</sup>

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<sup>1,3</sup>

Indication	Dose
All Indications	Administer 70 mg/m <sup>2</sup> intravenously every 14 days <u>Note:</u> Patients homozygous for the UGT1A1*28 allele: Administer 50 mg/m <sup>2</sup> every 14 days and may titrate up to 70 mg/m <sup>2</sup> 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<sup>®</sup>) irinotecan liposomal. National Comprehensive Cancer Network, 2023. The NCCN Compendium<sup>®</sup> is a derivative work of the NCCN Guidelines<sup>®</sup>. NATIONAL COMPREHENSIVE CANCER NETWORK<sup>®</sup>, NCCN<sup>®</sup>, and NCCN GUIDELINES<sup>®</sup> 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

## Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

*We* will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *contract*, *your* id card, or [aspirushealthplan.com](http://aspirushealthplan.com).

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator  
Aspirus Health Plan, Inc.  
PO Box 1062  
Minneapolis, MN 55440  
Phone: 1.866.631.5404 (TTY: 711)  
Fax: 763.847.4010  
Email: [customerservice@aspirushealthplan.com](mailto:customerservice@aspirushealthplan.com)

*You* can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

*You* can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

**Albanian:** KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

**Arabic:** تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

**French:** ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

**German:** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

**Hindi:** \_यान द\_ : य\_द आप िहंदी बोलते ह\_ तो आपके िलए मु\_त म\_ भाषा सहायता सेवाएं उपल\_ध ह\_। 1.866.631.5404 (TTY: 711) पर कॉल कर\_।

**Hmong:** LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

**Korean:** 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

**Polish:** UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

**Russian:** ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

**Spanish:** ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

**Tagalog:** PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

**Traditional Chinese:** 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY:711)。

**Vietnamese:** CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

**Pennsylvania Dutch:** Wann du Deitsch (Pennsylvania German / Dutch) schwetzsch, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

**Lao:** ໄປ່ດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY:711).