

## Irinotecan liposome injection (Onivyde®)

### Place of Service

Office Administration  
Home Infusion Administration  
Outpatient Facility Administration  
Infusion Center Administration

HCPCS: J9205 per 1 mg

### Condition listed in policy (see criteria for details)

- [Ampullary adenocarcinoma](#)
- [Pancreatic cancer](#)

**AHFS therapeutic class:** Antineoplastic agent

**Mechanism of action:** Topoisomerase inhibitor

### **(1) Special Instructions and Pertinent Information**

**Covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax.

### **(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for Onivyde® (irinotecan liposome injection) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

### Ampullary adenocarcinoma

1. Being used as subsequent therapy, **AND**
2. Being used in combination with fluorouracil and leucovorin

#### **Covered Doses**

Up to 70 mg/m<sup>2</sup> IV q 2 weeks

#### **Coverage Period**

Indefinite

#### **ICD-10:**

C24.1

### Pancreatic cancer

1. One of the following:
  - a) Second line therapy for locally advanced unresectable or metastatic disease after disease progression on one of the following:
    - (i) A fluoropyrimidine-based therapy (without prior irinotecan), OR

(ii) A gemcitabine-based therapy

OR

b) Therapy for recurrent disease

AND

2. Used in combination with fluorouracil and leucovorin

**Covered Doses**

Up to 70 mg/m<sup>2</sup> IV q 2 weeks

**Coverage Period**

Indefinite

**ICD-10:**

C25.0-C25.3, C25.7-C25.9, Z85.07

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for Onivyde® (irinotecan liposome injection) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

43 mg (single-dose vial)

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Onivyde® (irinotecan liposome) [Prescribing information]. Cambridge, MA: Ipsen Biopharmaceutical, Inc.; 2/2023.
- National Comprehensive Cancer Network. Pancreatic adenocarcinoma (Version 1.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Ampullary adenocarcinoma (Version 1.2023). Available at <http://www.nccn.org>.

**(7) Policy Update**

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity*

*Reviewed by P&T Committee*

PHP Medi-Cal

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