

Irinotecan liposome injection (Onivyde®)

Place of Service

Office Administration
Home Infusion Administration
Outpatient Facility Administration
Infusion Center Administration

HCPs: 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/m² 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/m² 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

Commercial

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