

## Clinical Policy: Irinotecan Liposome Injection (Onivyde)

Reference Number: PA.CP.PHAR.304

Effective Date: 01/18

Last Review Date: 11/17

[Coding Implications](#)

[Revision Log](#)

### Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness<sup>®</sup> clinical policy for irinotecan liposome injection (Onivyde<sup>™</sup>).

### Policy/Criteria

It is the policy of Pennsylvania Health and Wellness<sup>®</sup> that Onivyde is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Pancreatic Cancer (must meet all):

1. Diagnosis of pancreatic adenocarcinoma;
2. Disease has progressed on gemcitabine-based therapy;
3. Onivyde is prescribed in combination with fluorouracil and leucovorin;
4. No current bowel obstruction;
5. No history of severe hypersensitivity reaction to Onivyde or irinotecan HCl.

**Approval duration: 3 months**

**B. Other diagnoses/indications:** Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

#### II. Continued Approval

##### A. Pancreatic Cancer (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member has none of the following reasons to discontinue:
  - a. Disease progression or unacceptable toxicity;
  - b. Severe hypersensitivity reaction to Onivyde or irinotecan HCl;
  - c. Bowel obstruction;
  - d. Interstitial lung disease;
  - e. Third occurrence of any Grade 3\* (severe/hospitalization indicated) or Grade 4\* (life-threatening) adverse reaction.

---

\*National Cancer Institute Common Toxicity Criteria for Adverse Events, version 4.0.

**Approval duration: 6 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

## CLINICAL POLICY

### Irinotecan Liposome Injection

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

#### Background

##### *Description/Mechanism of Action:*

Irinotecan liposome injection is a topoisomerase 1 inhibitor encapsulated in a lipid bilayer vesicle or liposome. Topoisomerase 1 relieves torsional strain in DNA by inducing single-strand breaks. Irinotecan and its active metabolite SN-38 bind reversibly to the topoisomerase 1-DNA complex and prevent re-ligation of the single-strand breaks, leading to exposure time-dependent double-strand DNA damage and cell death. In mice bearing human tumor xenografts, irinotecan liposome administered at irinotecan HCl-equivalent doses 5-fold lower than irinotecan HCl achieved similar intratumoral exposure of SN-38.

##### *Formulations:*

Onivyde is available in a single-dose vial containing

- 43 mg irinotecan free base at a concentration of 4.3 mg/mL

##### *FDA Approved Indications:*

Onivyde is a topoisomerase inhibitor/intravenous formulation indicated

- In combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Limitation of use: Onivyde is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

#### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9205	Injection, irinotecan liposome, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date

**CLINICAL POLICY**  
**Irinotecan Liposome Injection**



**References**

1. Onivyde prescribing information. Cambridge, MA: Merrimack Pharmaceuticals, Inc.; October 2015. Available at [https://www.onivyde.com/\\_assets/pdf/ONIVYDE\\_USPI.pdf](https://www.onivyde.com/_assets/pdf/ONIVYDE_USPI.pdf). Accessed January 9, 2017.