

# Clinical Policy: Irinotecan Liposome Injection (Onivyde)

Reference Number: PA.CP.PHAR.304

Effective Date: 01/18

Last Review Date: 10/30/2019

[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>).

## FDA Approved Indication(s)

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

## 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 Adenocarcinoma (must meet all):

1. Diagnosis of pancreatic adenocarcinoma;
2. Prescribed with use in combination with fluorouracil and leucovorin;
3. Request meets one of the following (a or b):
  - a. Dose does not exceed 70 mg/m<sup>2</sup> every 2 weeks;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

#### B. Other diagnoses/indications: Refer to PA.CP.PMN.53

### II. Continued Approval

#### A. Pancreatic Adenocarcinoma (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 is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
  - a. New dose does not exceed 70 mg/m<sup>2</sup> every 2 weeks;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

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

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; or
2. Refer to PA.CP. PMN.53

**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

**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.

<b>HCPCS Codes</b>	<b>Description</b>
J9205	Injection, irinotecan liposome, 1 mg

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>Approval Date</b>
4Q 2018 annual review: removed requirement to check for contraindication bowel obstruction; added COC; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	07/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	

**References**

1. Onivyde Prescribing Information. Cambridge, MA: Merrimack Pharmaceuticals, Inc.; June 2017. Available at: [https://www.onivyde.com/\\_assets/pdf/ONIVYDE\\_USPI.pdf](https://www.onivyde.com/_assets/pdf/ONIVYDE_USPI.pdf). Accessed July 19, 2018.
2. Irinotecan liposome injection. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed July 19, 2018.
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