

## Clinical Policy: Irinotecan Liposome (Onivyde)

Reference Number: LA.PHAR.304

Effective Date: 11.04.23

Last Review Date: 04.22.24

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

\*\*Please note: This policy is for medical benefit\*\*

### Description

Irinotecan liposome injection (Onivyde®) is a topoisomerase inhibitor.

### FDA Approved Indication(s)

Onivyde is indicated, in:

- In combination with oxaliplatin, fluorouracil and leucovorin, for the first-line treatment of patients with metastatic pancreatic adenocarcinoma;
- In combination with fluorouracil and leucovorin, for the treatment of patients with metastatic pancreatic adenocarcinoma 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

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections that Onivyde is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

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

1. Diagnosis of locally advanced, metastatic, or recurrent pancreatic adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Prescribed in one of the following ways (a or b):
  - a. In combination with oxaliplatin, fluorouracil, and leucovorin (i.e., as a component of the NALIRIFOX regimen; *see Appendix D*) as first-line therapy;
  - b. In combination with fluorouracil and leucovorin for disease progression following gemcitabine-based therapy, or fluoropyrimidine-based therapy without prior irinotecan;
5. Request meets one of the following (a, b, or c):\*
  - a. Dose does not exceed 50 mg/m<sup>2</sup> every 2 weeks when used as a component of the NALIRIFOX regimen;

- b. Dose does not exceed 70 mg/m<sup>2</sup> every 2 weeks when prescribed in combination with fluorouracil and leucovorin only;
- c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Pancreatic Adenocarcinoma (must meet all):**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Onivyde for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):\*
  - a. New dose does not exceed 50 mg/m<sup>2</sup> every 2 weeks as a component of the NALIRIFOX regimen;
  - b. New dose does not exceed 70 mg/m<sup>2</sup> every 2 weeks in combination with fluorouracil and leucovorin only;
  - c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

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

1. this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of gemcitabine-containing regimens: gemcitabine alone or with any of the following: capecitabine, fluorouracil and leucovorin, albumin-bound paclitaxel and/or cisplatin, erlotinib, docetaxel and capecitabine	Varies	Varies
Examples of fluoropyrimidine-based regimens: fluorouracil with any of the following: leucovorin, irinotecan/ liposomal irinotecan, and oxaliplatin	Varies	Varies

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): severe hypersensitivity reaction to Onivyde or irinotecan HCl
- Boxed warning(s): severe neutropenia and severe diarrhea; do not administer in patients with bowel obstruction

*Appendix D: NALIRIFOX*

- NALIRIFOX regimen contains fluorouracil, leucovorin, liposomal irinotecan, and oxaliplatin

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Pancreatic adenocarcinoma	<ul style="list-style-type: none"> <li>• 50 mg/m<sup>2</sup> IV every 2 weeks when used prior to leucovorin, fluorouracil, and oxaliplatin</li> <li>• 70 mg/m<sup>2</sup> IV every 2 weeks when used prior to leucovorin and fluorouracil only</li> <li>• If homozygous for UGT1A1*28 allele: 50 mg/m<sup>2</sup> IV every 2 weeks. Increase the dose to 70 mg/m<sup>2</sup> as tolerated in subsequent cycles.</li> </ul>	70 mg/m <sup>2</sup> every 2 weeks

**VI. Product Availability**

Single-dose vial: 43 mg/10 mL

**VII. References**

1. Onivyde Prescribing Information. Cambridge, MA: Merrimack Pharmaceuticals, Inc.; February 2023. Available at: <https://www.onivyde.com>. Accessed February 21, 2024.
2. 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 February 21, 2024.
3. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 1.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/pancreatic.pdf](https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf). Accessed February 21, 2024.

**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	LDH Approval Date
Converted corporate to local policy.	06.15.23	10.05.23
Added newly FDA-approved use as first-line use when prescribed in combination with oxaliplatin, fluorouracil, and leucovorin for metastatic disease	04.22.24	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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