

## Medical Policy: Onivyde® (irinotecan liposome)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.158	January 31, 2024	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

### Definitions

Onivyde (irinotecan liposome) is irinotecan, a topoisomerase inhibitor, encapsulated in lipid bilayer vesicle or liposome. The lipid bilayer vesicle allows higher concentrations in the body with lower doses compared to irinotecan HCL (non liposomal formulation).

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.

### Length of Authorization

Coverage will be provided for 6 months and may be renewed.

### Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

172 billable units per 14 days

## Guideline

### I. Initial Approval Criteria

**Onivyde** may be considered medically necessary if one of the below conditions are met **AND** use is consistent with the medical necessity criteria that follows:

1. **Metastatic Adenocarcinoma of the Pancreas**

- A. Onivyde (irinotecan liposome) must be used in combination with fluorouracil and leucovorin; **AND**
- B. Member must have progressed on prior treatment of a gemcitabine-based therapy; **AND**
- C. Member must **not** have failed prior therapy with irinotecan HCL (non liposomal formulation).

### Limitations/Exclusions

Onivyde (irinotecan liposome) is not considered medically necessary when any of the following selection criteria is met:

- 1. Disease progression while taking Onivyde (irinotecan liposome)
- 2. Disease progression while taking irinotecan HCL (non liposomal formulation)
- 3. Dosing exceeds single dose limit of Onivyde (irinotecan liposome)
  - a. 70 mg/m<sup>2</sup>
- 4. Member with absolute neutrophil count below 1500/mm<sup>2</sup> or neutropenic fever
- 5. Member with bowel obstruction
- 6. Member with diarrhea of Grade 2-4 severity
- 7. Onivyde (irinotecan liposome) **CANNOT** be substituted for irinotecan HCL (non liposomal formulation)
- 8. Member with hypersensitivity to Onivyde (irinotecan liposome) or irinotecan HCL (non liposomal formulation)
- 9. Member with interstitial lung disease
  - a. Withhold Onivyde (irinotecan liposome) in member with new or progressive dyspnea, cough, and fever, pending diagnostic evaluation
- 10. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

### II. Renewal Criteria

- 1. Patient continues to meet initial approval criteria; **AND**
- 2. Tumor response with stabilization of disease or decrease in tumor spread or size.

### Dosage/Administration

Indication	Dose
Pancreatic Cancer	70 mg/m <sup>2</sup> intravenously every 14 days 50 mg/m <sup>2</sup> intravenously every 14 days for member with homozygous for UGT1A1*28 allele.

## Applicable Procedure Codes

Code	Description
J9205	Injection, irinotecan liposome, 1 mg, 1 billable unit = 1 mg

## Applicable NDCs

Code	Description
15054-0043-01	Onivyde 43 mg/10 ml single dose vial

## ICD-10 Diagnoses

Code	Description
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
Z85.07	Personal history of malignant neoplasm of pancreas

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/31/2024	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	5/30/2023	Annual review: no criteria changes
EmblemHealth & ConnectiCare	09/14/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	07/15/2019	Annual review

## References

1. Onivyde prescribing information. Merrimack Pharmaceuticals, Inc. October 2016.
2. Clinical Pharmacology Elsevier Gold Standard. 2017.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2017.
4. UpToDate, Waltham, MA. (Accessed on January 19, 2016.)
5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2017.