Medical Policy:
Onivyde® (irinotecan liposome)

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

Definitions

Onivyde (irinotecan liposome) is irinotecan, a topoisomerase inhibitor, encapsulated in lipid bilayer vesicle or lipsome. 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^2
4. Member with absolute neutrophil count below 1500/mm^2 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^2 intravenously every 14 days 50 mg/m^2 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.