

Drug Policy:

Onivyde™ (irinotecan liposome)

POLICY NUMBER UM ONC_1276	SUBJECT Onivyde™ (irinotecan liposome)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 03/23/16, 01/05/17, 01/02/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21	APPROVAL DATE October 13, 2021	EFFECTIVE DATE October 29, 2021	COMMITTEE APPROVAL DATES 03/23/16, 01/05/17, 01/02/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Onivyde (irinotecan liposome) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines](#) shall follow [NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Metastatic Adenocarcinoma of the Pancreas

1. Onivyde (irinotecan liposome) may be used for members with metastatic pancreas cancer who have progressed on prior therapy with both a gemcitabine-based regimen (e.g., gemcitabine + nab-paclitaxel) **AND** FOLFIRINOX (except when patient was felt to be unfit for this regimen) **AND**
2. Onivyde (I irinotecan liposome) will be used in combination with 5-FU (fluorouracil) and leucovorin.

III. EXCLUSION CRITERIA

- A. Disease progression while taking Onivyde (irinotecan liposome).
- B. Dosing exceeds single dose limit of Onivyde (irinotecan liposome) 70 mg/m².
- C. Onivyde (irinotecan liposome) **CANNOT** be substituted for irinotecan HCL (non-liposomal formulation).
- D. Member with hypersensitivity or contraindications to Onivyde (irinotecan liposome) or irinotecan HCL (non-liposomal formulation).
- E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Onivyde prescribing information. Merrimack Pharmaceuticals, Inc. 2020.
- B. Clinical Pharmacology Elsevier Gold Standard 2021.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.
- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.