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	**APPROVAL DATE** November 11, 2020	**EFFECTIVE DATE** November 30, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 03/23/16, 01/05/17, 01/02/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20	
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 available, generic alternatives are preferred over brand-name drugs.

B. Metastatic Adenocarcinoma of the Pancreas

1. NOTE: Onyvide (liposomal irinotecan) is a non-preferred drug per NCH Policy and NCH Pathways.
2. Onyvide (liposomal irinotecan) 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).
3. Onyvide (liposomal irinotecan) will be used 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/m^2.

C. Onivyde (irinotecan liposome) CANNOT be substituted for irinotecan HCL (non-liposomal formulation).

D. Member with hypersensitivity 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. 2018.

B. Clinical Pharmacology Elsevier Gold Standard. 2020.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.