Drug Policy:

Onivyde™ (irinotecan liposome)

POLICY NUMBER UM ONC_1276	SUBJECT Onivyde™ (irinotecan liposome)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
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, 11/15/21, 05/11/22, 10/12/22, 11/09/22, 11/08/23, 12/13/23, 12/12/24	APPROVAL DATE December 12, 2024	EFFECTIVE DATE December 27, 2024	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, 11/15/21, 05/11/22, 10/12/22, 11/09/22, 11/08/23, 12/22/23, 12/12/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses clinical guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this clinical guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their plan customer service representative for specific coverage information.

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.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent 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. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Adenocarcinoma of the Pancreas and Ampullary Adenocarcinoma

1. Onivyde (irinotecan liposome) may be used for adult members with recurrent/metastatic adenocarcinoma of the pancreas or ampullary adenocarcinoma who have progressed on prior therapy with a gemcitabine-based regimen (e.g., gemcitabine +/- nab-paclitaxel) AND
2. Onivyde (irinotecan liposome) will be used in combination with 5-FU (fluorouracil) and leucovorin.
3. NOTE: Onivyde (irinotecan liposome) is not supported by Evolent Policy in combination with oxaliplatin, 5-FU (fluorouracil), and leucovorin for the first-line treatment of metastatic pancreatic adenocarcinoma. This policy position is based on the lack of Level 1 Evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes compared to Evolent recommended alternative agents/regimens available at: https://www.evolent.com/pathways.

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 or contraindications to Onivyde (irinotecan liposome) or irinotecan HCL (non-liposomal formulation).

E. Investigational use of Onivyde (irinotecan liposome) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. CODING INFORMATION

HCPCS Code	Description
J9205	Injection, irinotecan liposome, 1 mg

V. MEDICATION MANAGEMENT

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

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. Wang-Gillam A, et al. NAPOLI-1 phase 3 study of liposomal irinotecan in metastatic pancreatic cancer: Final overall survival analysis and characteristics of long-term survivors. Eur J Cancer. 2019 Feb;108:78-87.

B. Wang-Gillam A, et al. NAPOLI-1 Clinical Trial. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. Lancet. 2016 Feb 6;387(10018):545-557.

C. Wainberg ZA, et al. NALIRIFOX versus nab-paclitaxel and gemcitabine in treatment-naive patients with metastatic pancreatic ductal adenocarcinoma (NAPOLI 3): a randomised, open-label, phase 3 trial. Lancet. 2023 Oct 7;402(10409):1272-1281. doi: 10.1016/S0140-6736(23)01366-1

D. Onivyde prescribing information 2024. Ipsen Biopharmaceuticals, Inc. Cambridge, MA.

E. Clinical Pharmacology Elsevier Gold Standard 2024.

F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2024.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2024.

I. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

J. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

K. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.