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 is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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
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 fluoropyrimidine or gemcitabine-based therapy AND
   c. Member must NOT have failed prior therapy with irinotecan HCL (non-liposomal formulation).

III. EXCLUSION CRITERIA
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) 70 mg/m².
4. Onivyde (irinotecan liposome) CANNOT be substituted for irinotecan HCL (non-liposomal formulation).
5. Member with hypersensitivity to Onivyde (irinotecan liposome) or irinotecan HCL (non-liposomal formulation).
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT
Please refer to the FDA label/package insert for details regarding these topics.
V. APPROVAL AUTHORITY
1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS
None

VII. REFERENCES