**POLICY:** Oncology – Onivyde® (irinotecan liposome injection – Ipsen Biopharmaceuticals)

**APPROVAL DATE:** 04/24/2019

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**OVERVIEW**
Onivyde is a topoisomerase 1 inhibitor formulated into a liposomal dispersion for intravenous (IV) use. Topoisomerase 1 inhibitors prevent the repair of breaks in single-strands of DNA, eventually leading to double-strand damage to DNA and cell death.

Onivyde is indicated, in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. Limitation of use: Onivyde is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

**Guidelines**

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**POLICY STATEMENT**
Prior authorization is recommended for medical benefit coverage of Onivyde. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Onivyde as well as the monitoring required for adverse events and long-term efficacy, approval requires Onivyde to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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**RECOMMENDED AUTHORIZATION CRITERIA**
Coverage of Onivyde is recommended in those who meet the following criteria:

**FDA-Approved Indications**

1. **Pancreatic Adenocarcinoma, Locally Advanced or Metastatic.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient has tried at least one chemotherapy regimen for pancreatic adenocarcinoma, either gemcitabine-based chemotherapy, or fluoropyrimidine-based chemotherapy without irinotecan; AND
   B) Onivyde will be used in combination with fluorouracil and leucovorin; AND
   C) Onivyde is prescribed by or in consultation with an oncologist.
**Dosing.** Approve the following dosing regimens (A and B):

A) Each individual dose must not exceed 70 mg/m$^2$ administered intravenously; AND

B) The dose is administered no more frequently than once every 2 weeks.\(^1\)

Note: Dose modifications are recommended for Grade 3 or 4 adverse events, interstitial lung disease and anaphylactic reactions.\(^1\) See the prescribing information for more detail.

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**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Onivyde has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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**REFERENCES**


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**HISTORY**

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04/24/2019