# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Injectable) – Onivyde Prior Authorization Policy
- Onivyde® (irinotecan liposome intravenous infusion – Ipsen)

**REVIEW DATE:** 04/20/2022

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## OVERVIEW

Onivyde, a topoisomerase inhibitor, 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.[1] Limitation of use: Onivyde is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

## Guidelines

The National Comprehensive Cancer Network has addressed Onivyde for the following indications:

- The **ampullary adenocarcinoma** clinical practice guidelines (version 1.2022 – March 9, 2022) recommend Onivyde, in combination with fluorouracil and leucovorin, for the subsequent treatment of disease progression in patients with pancreatobiliary and mixed type disease with good performance status (defined as Eastern Cooperative Oncology Group [ECOG] performance status of 0 or 1, good biliary drainage, and adequate nutritional intake) [category 2A].[3,4]
- The **hepatobiliary cancers** clinical practice guidelines (version 1.2022 – March 9, 2022) recommend Onivyde in combination with fluorouracil and leucovorin for the subsequent treatment of unresectable or metastatic biliary tract cancers (category 2B).[3,5]
- The **pancreatic adenocarcinoma** clinical practice guidelines (version 1.2022 – February 24, 2022) recommend Onivyde, in combination with fluorouracil and leucovorin, for the subsequent treatment of locally advanced (category 2A), or metastatic (category 1) pancreatic adenocarcinoma in patients with ECOG performance status of 0 to 2.[2,3]

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Onivyde. 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.

**Automation**: None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Onivyde is recommended in those who meet one of the following criteria:

### FDA-Approved Indication

1. **Pancreatic Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND

**C)** Patient has tried at least one of the following chemotherapy regimens for pancreatic adenocarcinoma (i or ii):
  **i.** Gemcitabine-based chemotherapy; OR
  **ii.** Fluoropyrimidine-based chemotherapy without irinotecan; AND
**D)** Onivyde will be used in combination with fluorouracil and leucovorin; AND
**E)** Onivyde is prescribed by or in consultation with an oncologist.

**Other Uses with Supportive Evidence**

**2. Ampullary Adenocarcinoma**. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
**A)** Patient is ≥ 18 years of age; AND
**B)** Patient has tried at least of the following chemotherapy regimens (i, ii, or iii):
  **i.** Gemcitabine-based therapy; OR
  **ii.** Fluoropyrimidine-based therapy, if no prior irinotecan; OR
  **iii.** Oxaliplatin-based therapy, if no prior irinotecan; AND
**C)** Onivyde will be used in combination with fluorouracil and leucovorin; AND
**D)** Onivyde is prescribed by or in consultation with an oncologist.

**3. Biliary Tract Cancer**. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
**A)** Patient is ≥ 18 years of age; AND
**B)** Patient has one of the following (i, ii, or iii):
  **i.** Gallbladder cancer; OR
  **ii.** Extrahepatic cholangiocarcinoma; OR
  **iii.** Intrahepatic cholangiocarcinoma; AND
**C)** Patient has disease progression on or after systemic therapy; AND
  Note: Examples of systemic therapy include gemcitabine, cisplatin, fluorouracil, and capecitabine.
**D)** Onivyde is used in combination with fluorouracil and leucovorin; AND
**E)** The medication is prescribed by or in consultation with an oncologist.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage for Onivyde is not recommended in the following situations:

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

## REFERENCES

1. Onivyde® liposome intravenous infusion [prescribing information]. Basking Ridge, NJ: Ipsen; June 2017.
2. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2022 – February 24, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 6, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 6, 2022. Search term: irinotecan liposome.
4. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 7, 2022.
5. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 1.2022 – March 29, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 7, 2022.