Utilization Review Policy 176

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

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW
Onivyde, a topoisomerase inhibitor, is indicated for the treatment of **metastatic pancreatic adenocarcinoma**:[1]

- In combination with fluorouracil and leucovorin in adults after disease progression following gemcitabine-based therapy.
- In combination with oxaliplatin, fluorouracil, and leucovorin for first-line treatment of adults.

Limitation of use: Onivyde is not indicated as a single agent for the treatment of patients with metastatic pancreatic adenocarcinoma.

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

- **Ampullary adenocarcinoma:** Clinical practice guidelines (version 1.2024 – December 13, 2023) 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]
- **Biliary tract cancers:** Clinical practice guidelines (version 3.2023 – November 8, 2023) recommend Onivyde in combination with fluorouracil and leucovorin for the subsequent treatment of unresectable, resected gross residual, or metastatic biliary tract cancers (category 2B).[3,5]
- **Pancreatic adenocarcinoma:** Clinical practice guidelines (version 1.2024 – December 13, 2023) recommend Onivyde, in combination with fluorouracil and leucovorin, for the first-line and 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 medical benefit coverage of Onivyde. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. 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.

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 (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND
   - **C)** Onivyde will be used in combination with fluorouracil and leucovorin; AND
   - **D)** Onivyde is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 70 mg/m^2 administered intravenously no more frequently than once every 2 weeks.

Other Uses with Supportive Evidence

2. **Ampullary Adenocarcinoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least ONE 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.

   Dosing. Approve up to 70 mg/m^2 administered intravenously no more frequently than once every 2 weeks.

3. **Biliary Tract Cancer**. Approve for 1 year if the patient meets ALL of the following (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.

   Dosing. Approve up to 70 mg/m^2 administered intravenously no more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of 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; February 2024.
2. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – December 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 23, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2024. Search term: irinotecan liposome.
4. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – December 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 23, 2024.
5. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 3.2023 – November 8, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/19/2023
Early Annual Revision	**Pancreatic Adenocarcinoma:** Removed requirement that the patient has tried gemcitabine based chemotherapy or fluoropyrimidine based chemotherapy without irinotecan.	02/28/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024