Irinotecan Liposome Injection (Onivyde®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Onivyde, is indicated, in combination with oxaliplatin, fluorouracil, and leucovorin for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma.
- Onivyde is indicated, in combination with fluorouracil and leucovorin, for the treatment of adult patients with metastatic pancreatic adenocarcinoma 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 pancreatic adenocarcinoma.

Compendial Uses

- Locally advanced, recurrent, or metastatic pancreatic adenocarcinoma
- Ampullary Adenocarcinoma
- Biliary Tract Cancers
  - Intrahepatic Cholangiocarcinoma
  - Extrahepatic Cholangiocarcinoma
  - Gallbladder Cancer

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA

Pancreatic Adenocarcinoma

- Authorization of 12 months may be granted for the first-line therapy for metastatic pancreatic adenocarcinoma when used in combination with oxaliplatin, fluorouracil, and leucovorin.
- Authorization of 12 months may be granted for the first-line therapy, or as induction therapy followed by chemoradiation for locally advanced pancreatic adenocarcinoma when used in combination with oxaliplatin, fluorouracil, and leucovorin. Authorization of 12 months may be granted for treatment of locally advanced, recurrent, or metastatic pancreatic adenocarcinoma when used in combination with fluorouracil and leucovorin.

Ampullary Adenocarcinoma

Authorization of 12 months may be granted for subsequent treatment of ampullary adenocarcinoma when used in combination with fluorouracil and leucovorin.

Biliary Tract Cancers

Authorization of 12 months may be granted for subsequent treatment of unresectable or resected gross residual (R2), or metastatic intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer when used in combination with fluorouracil and leucovorin.

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Onivyde
- Onivyde is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen AND
  - No evidence of disease progression while on the current regimen

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Onivyde [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; February 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 2, 2024.

EFFECTIVE DATE 7/1/2025

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