Reference number(s)
4374-A

Standard Medicare Part B Management Onivyde

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Onivyde	irinotecan liposome	injection

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[1]

- 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[2]

- Locally advanced, recurrent, or metastatic pancreatic adenocarcinoma

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- Ampullary Adenocarcinoma
- Biliary Tract Cancers
    - Intrahepatic Cholangiocarcinoma
    - Extrahepatic Cholangiocarcinoma
    - Gallbladder Cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Pancreatic Adenocarcinoma[1,2]

- 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[2]

- Authorization of 12 months may be granted for subsequent treatment of ampullary adenocarcinoma when used in combination with fluorouracil and leucovorin.
- Authorization of 12 months may be granted for the first-line therapy of metastatic ampullary adenocarcinoma when used in combination with oxaliplatin, fluorouracil, and leucovorin.

Biliary Tract Cancers[2]

Authorization of 12 months may be granted for subsequent treatment of unresectable or 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:

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- 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.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Onivyde.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Ampullary Adenocarcinoma
- NCCN Guideline: Pancreatic adenocarcinoma
- NCCN Guideline: Biliary Tract cancers

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Onivyde are covered in addition to the following:

- Ampullary adenocarcinoma
- Locally advanced, recurrent, or metastatic pancreatic adenocarcinoma
- Biliary Tract cancers

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Onivyde to treat locally advanced, recurrent and metastatic pancreatic adenocarcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Onivyde for subsequent treatment of ampullary adenocarcinoma or to treat metastatic ampullary adenocarcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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Support for using Onivyde as subsequent treatment of unresectable or gross residual (R2) or metastatic biliary tract cancers can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Onivyde [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; December 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 29, 2025.

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