Reference number(s)
4374-A

STANDARD MEDICARE PART B MANAGEMENT

ONIVYDE (irinotecan liposome injection)

POLICY

I. 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.

A. FDA-Approved Indication

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.

B. Compendial Uses

1. Locally advanced, recurrent, or metastatic adenocarcinoma of the pancreas
2. Ampullary Adenocarcinoma
3. Hepatobiliary Cancers
   a. Intrahepatic Cholangiocarcinoma
   b. Extrahepatic Cholangiocarcinoma
   c. Gallbladder Cancer

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

II. CRITERIA FOR INITIAL APPROVAL

1. Adenocarcinoma of the Pancreas

Authorization of 12 months may be granted for treatment of locally advanced, recurrent, or metastatic adenocarcinoma of the pancreas when used in combination with fluorouracil and leucovorin.

2. Ampullary Adenocarcinoma

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

3. Hepatobiliary Cancers

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

III. 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:
1. The member is currently receiving therapy with Onivyde
2. Onivyde is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen AND
    ii. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Onivyde.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Ampullary Adenocarcinoma
4. NCCN Guideline: Pancreatic adenocarcinoma
5. NCCN Guideline: Hepatobiliary 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:

A. Ampullary adenocarcinoma
B. Locally advanced, recurrent, or metastatic adenocarcinoma of the pancreas
C. Hepatobiliary cancers

V. EXPLANATION OF RATIONALE

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

Support for 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).

Support for locally advanced, recurrent, or 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).

Support for hepatobiliary cancer 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).

VI. REFERENCES

1. Onivyde [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc; June 2017.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 29, 2022.