VENTURA COUNTY
HEALTH CARE PLAN

Utilization Review Policy

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

DATE REVIEWED: 04/22/2020

OVERVIEW

Onivyde is a topoisomerase 1 inhibitor formulated into a liposomal dispersion for intravenous (IV) use.[1] Topoisomerase 1 inhibitors prevent the repair of breaks in single-strands of DNA, eventually leading to double-strand damage to DNA and cell death.

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.[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 (NCCN) Pancreatic Adenocarcinoma practice guidelines (Version 1.2020 – November 26, 2019) recommend Onivyde, in combination with fluorouracil and leucovorin, for the second-line treatment of locally advanced, or metastatic pancreatic adenocarcinoma in patients with Eastern Cooperative Oncology Group (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 indication(s). 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Pancreatic Adenocarcinoma, Locally Advanced or Metastatic.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient has tried at least one chemotherapy regimen for pancreatic adenocarcinoma, either gemcitabine-based chemotherapy, or fluoropyrimidine-based chemotherapy without irinotecan; AND
   - **B)** Onivyde will be used in combination with fluorouracil and leucovorin; AND
   - **C)** Onivyde is prescribed by or in consultation with an oncologist.

   Dosing. Approve the following dosing regimens (A and B):

A) Each individual dose must not exceed 70 mg/m^2 administered intravenously; AND
B) The dose is administered no more frequently than once every 2 weeks.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Onivyde has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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 injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals; June 2017.
2. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (Version 1.2020 – November 26, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed April 17, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 17, 2020. Search term: irinotecan liposome.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New Policy	--	04/24/2019
Annual Revision	No criteria change.	04/22/2020