BlueCross BlueShield Federal Employee Program

ONIVYDE
(irinotecan liposome injection)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Onivyde is a topoisomerase 1 inhibitor used to treat patients with metastatic pancreatic adenocarcinoma. Onivyde inhibits topoisomerase 1, an enzyme involved in DNA untangling during DNA replication, leading to decreased DNA replication and cancer cell death. The drug is administered via intravenous infusion over 90 minutes every two weeks until disease progression or unacceptable toxicity (1).

Regulatory Status

FDA-approved indication: Onivyde is a topoisomerase inhibitor indicated: (1)

- In combination with oxaliplatin, fluorouracil, and leucovorin, for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma.
- In combination with fluorouracil and leucovorin, for the treatment of 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 (1).

The Onivyde label includes a boxed warning citing the risk of severe neutropenia (low neutrophil count) and severe diarrhea. Onivyde can cause severe neutropenia and neutropenic sepsis. Monitor complete blood cell counts on Days 1 and 8 of every cycle and more frequently if clinically indicated. Withhold Onivyde for absolute neutrophil count (ANC) below 1500/mm^3 or neutropenic fever. Resume Onivyde when ANC is 1500/mm^3 or greater. Reduce Onivyde dose for Grade 3-4 neutropenia or neutropenic fever following recovery in subsequent cycles. Onivyde can also cause severe diarrhea. Do not administer Onivyde to patients with bowel obstruction. Withhold Onivyde for diarrhea of Grade 2-4 severity (1).

Onivyde can cause severe interstitial lung disease (ILD). Withhold Onivyde in patients with new or progressive dyspnea, cough, and fever, pending diagnostic evaluation. Discontinue Onivyde in patients with a confirmed diagnosis of ILD (1).

Onivyde can cause fetal harm. Female patients should be advised to use effective contraception during treatment with Onivyde and for 7 months following the last dose (1).

Safety and effectiveness in pediatric patients have not been established (1).

Summary

Onivyde is a topoisomerase 1 inhibitor used to treat metastatic pancreatic adenocarcinoma. Onivyde carries a boxed warning for severe neutropenia and severe diarrhea. Onivyde is not to be administered to patients with bowel obstruction. Onivyde can cause severe interstitial lung disease. Onivyde can cause fetal harm and female patients should be advised to use effective contraception during treatment and for 7 months after the last dose. The safety and effectiveness of Onivyde in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Onivyde while maintaining optimal therapeutic outcomes.

References

1. Onivyde [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; February 2024.
2. NCCN Drugs & Biologics Compendium® Irinotecan 2024. National Comprehensive Cancer Network, Inc. Accessed on May 14, 2024.