ATRIO HEALTH PLANS

Pancreatic Cancer
Onivyde (irinotecan liposome) J9205
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

- ☐ Diagnosis is adenocarcinoma of the pancreas
- ☐ Patient has metastatic disease?
- ☐ Patient was previously treated with a gemcitabine-based therapy
  - ☐ Patient had disease progression after this therapy
- ☐ Onivyde be given in combination with both fluorouracil (5-FU) and leucovorin

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Patient had an adequate response or significant improvement while on this medication.
If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____**Date:**_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

Prior Authorization Group – Pancreatic Cancer Drug PA

Drug Name(s):
ONIVYDE **IRINIOTECAN LIPOSOME**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:
N/A

Prescriber Restrictions:
Gastroenterologist, Oncologist or other pancreatic cancer specialist

Coverage Duration:
Initial Approval will be for 6 months
Continuation will be approved for 12 months

FDA Indications:
Onivyde

- Adenocarcinoma of pancreas, Metastatic progressive disease following gemcitabine-based therapy; In combination with fluorouracil and leucovorin

Off-Label Uses:
N/A

Age Restrictions:
N/A

Other Clinical Consideration:
Black Box Warning:

Fatal neutropenic sepsis occurred in 0.8% of patients receiving irinotecan liposome. Severe or life-threatening neutropenic fever or sepsis occurred in 3% and severe or life-threatening neutropenia occurred in 20% of patients receiving irinotecan liposome in combination with fluorouracil and leucovorin. Withhold irinotecan liposome for absolute neutrophil count below 1500/mm(3) or neutropenic fever. Monitor blood cell counts periodically during treatment.

Severe diarrhea occurred in 13% of patients receiving irinotecan liposome in combination with fluorouracil and leucovorin. Do not administer irinotecan liposome to patients with bowel obstruction. Withhold irinotecan liposome for diarrhea of Grade 2 to 4 severity. Administer loperamide for late diarrhea of any severity. Administer atropine, if not contraindicated, for early diarrhea of any severity

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/6E0D49/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/D360D7/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931642&contentSetId=100&title=Irinotecan+Liposome&servicesTitle=Irinotecan+Liposome&brandName=Onivyde&UserMdxSearchTerm=onivyde&=null#