



## **Pre - PA Allowance**

None

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## **Prior-Approval Requirements**

**Age** 18 years of age or older

### **Diagnosis**

Patient must have the following:

Metastatic pancreatic adenocarcinoma

**AND ALL** of the following:

1. Patient has **ONE** of the following:
  - a. First-line treatment **AND** used in combination with oxaliplatin, fluorouracil, and leucovorin
  - b. Disease progression following gemcitabine-based therapy **AND** used in combination with fluorouracil and leucovorin
2. Complete blood counts will be evaluated at Day 1 and Day 8 of each cycle
3. Prescriber agrees to withhold Onivyde if patient experiences diarrhea Grade 2-4 severity
4. Absolute neutrophil count (ANC)  $\geq 1500/\text{mm}^3$  and prescriber agrees to monitor neutrophil count before each dose
5. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Onivyde and for 7 months after the last dose

**AND NONE** of the following:

1. Bowel obstruction
2. Diagnosis of clinically significant (symptomatic or debilitating) interstitial lung disease (ILD)

## **Prior - Approval Limits**

**Duration** 12 months

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## **Prior – Approval *Renewal* Requirements**

**Age** 18 years of age or older

**ONIVYDE  
(irinotecan liposome injection)****Diagnosis**

Patient must have the following:

Metastatic pancreatic adenocarcinoma

**AND ALL** of the following:

1. **NO** disease progression or unacceptable toxicity
2. Used in combination with fluorouracil and leucovorin
3. Complete blood counts will be evaluated at Day 1 and Day 8 of each cycle
4. Prescriber agrees to withhold Onivyde if patient experiences diarrhea Grade 2-4 severity
5. Prescriber agrees to monitor neutrophil count before each dose
6. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Onivyde and for 7 months after the last dose

**AND NONE** of the following:

1. Bowel obstruction
2. Diagnosis of clinically significant (symptomatic or debilitating) interstitial lung disease (ILD)

**Prior - Approval *Renewal* Limits**

Same as above