RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Irinotecan Liposome (Onivyde)**
Policy Number: **RxA.430**
Drug(s) Applied: **Irinotecan liposome injection (Onivyde™)**
Last Review Date: **01/2020**
Line of Business: **Medicaid, HIM-Medical Benefit**

Background

Irinotecan liposome injection (Onivyde™) is a topoisomerase inhibitor.

It 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(s) of use: Onivyde is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

Indication	Dosing Regimen	Maximum Dose
Pancreatic adenocarcinoma	• 70 mg/m^2 IV every 2 weeks prior to leucovorin and fluorouracil • If homozygous for UGT1A1*28 allele: 50 mg/m^2 IV every 2 weeks. Increase the dose to 70 mg/m^2 as tolerated in subsequent cycles.	70 mg/m^2 every 2 weeks

Single-dose vial: 43 mg/10 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Pancreatic Adenocarcinoma (must meet all)**:**

1. Diagnosis of pancreatic adenocarcinoma;
2. Age ≥ 18 years;
3. Prescribed with use in combination with fluorouracil and leucovorin;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 70 mg/m^2 every 2 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

II. Continued Therapy

A. Pancreatic Adenocarcinoma (must meet all)**:**

1. Currently receiving medication via Rxadvance benefit, or documentation supports that member is currently receiving Onivyde for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 70 mg/m^2 every 2 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

III. Appendices

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): severe neutropenia and severe diarrhea; do not administer in patients with bowel obstruction.

References

1. Onivyde Prescribing Information. Cambridge, MA: Merrimack Pharmaceuticals, Inc.; June 2017. Available at: https://www.onivyde.com/. Accessed August 13, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 13, 2019.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020