Clinical Policy: Irinotecan Liposome (Onivyde)

Reference Number: CP.PHAR.304
Effective Date: 02.01.17
Last Review Date: 11.17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

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.

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

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Onivyde is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of pancreatic adenocarcinoma;
2. Age ≥ 18 years;
3. Meets (a or b):
   a. FDA approved use:
      i. In combination with fluorouracil and leucovorin, for metastatic disease after disease progression following gemcitabine-based therapy;
   b. NCCN recommended use:
      i. In combination with fluorouracil and leucovorin for locally advanced unresectable or metastatic disease after disease progression following fluoropyrimidine-based therapy without irinotecan or with gemcitabine-based therapy;
4. At the time of request, member has none of the following contraindications:
   a. Bowel obstruction;
5. 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).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 for specialty if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
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).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pancreatic adenocarcinoma	Administer Onivyde prior to leucovorin and fluorouracil. • 70 mg/m^2 administered by intravenous infusion over 90 minutes every 2 weeks. • Recommended starting dose if homozygous for the UGT1A1*28 allele is 50 mg/m^2 administered by	70 mg/m^2 every 2 weeks.

	intravenous infusion over 90 minutes. Increase the dose to 70 mg/m^2 as tolerated in subsequent cycles. • There is no recommended dose if serum bilirubin is above the upper limit of normal. Premedication: Administer a corticosteroid and an anti-emetic 30 minutes prior to Onivyde infusion.	

VI. Product Availability

Single-dose vial: 43 mg (4.3 mg/mL)

VII. References

1. Onivyde Prescribing Information. Cambridge, MA: Merrimack Pharmaceuticals, Inc.; October 2015. Available at: https://www.onivyde.com/_assets/pdf/ONIVYDE_USPI.pdf. Accessed August 2017.
2. Irinotecan liposome injection. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed August 2017.
3. Pancreatic adenocarcinoma (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed August 2017.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9205	Injection, irinotecan liposome, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.182 Excellus Oncology.	01.01.17	02.17
Age and dosing added. Hypersensitivity and reasons to discontinue removed. NCCN recommended uses added separately.	09.05.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.