Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2020**
Policy Number: PA.CP.PHAR.304	**Effective Date: 01/2018** **Revision Date: 10/2020**
Policy Name: Irinotecan Liposome Injection (Onivyde)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2020 annual review: added oncologist prescriber requirement; added age limit; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:**

Clinical Policy: Irinotecan Liposome Injection (Onivyde)

Reference Number: PA.CP.PHAR.304
Effective Date: 01/18
Last Review Date: 10/2020

Coding Implications
Revision Log

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.

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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® 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. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed for use in combination with fluorouracil and leucovorin;
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: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP. PMN.53

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 policies – PA.CP.PMN.53

IV. Appendices/General Information

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): severe hypersensitivity reaction to Onivyde or irinotecan HCl
- Boxed warning(s): severe neutropenia and severe diarrhea; do not administer in patients with bowel obstruction

V. Dosage and Administration

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

VI. Product Availability

Single-dose vial: 43 mg/10 mL

VII. References

1. Onivyde Prescribing Information. Cambridge, MA: Merrimack Pharmaceuticals, Inc.; June 2017. Available at: https://www.onivyde.com/. Accessed July 13, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 13, 2020.

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	Approval Date
4Q 2018 annual review: removed requirement to check for contraindication bowel obstruction; added COC; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	07/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
4Q 2020 annual review: added oncologist prescriber requirement; added age limit; references reviewed and updated.	10/2020	