Approved Revision: Do Not Implement until 8/31/21

Irinotecan Liposome Injection (Onivyde®)

NDC CODE(S) 15054-0043-XX - ONIVYDE 43MG/10ML Solution (IPSEN BIOPHARMACEUTICALS)

DESCRIPTION

Irinotecan liposome injection is an antineoplastic agent composed of the topoisomerase 1 inhibitor irinotecan hydrochloride (HCl) encapsulated in a lipid bilayer vesicle or liposome. Topoisomerase 1 is an enzyme which relieves torsional strain in DNA by inducing reversible single-strand breaks. Irinotecan induces double-strand DNA damage, breakage, and eventual cell death by binding to the topoisomerase 1-DNA complex and preventing re-ligation of the single-strand breaks. By adding the lipid bilayer vesicle, irinotecan remains in circulation for a longer time, increasing the potency of a smaller dose of the highly toxic irinotecan HCl.

POLICY

- Irinotecan liposome injection for the treatment of adenocarcinoma of the pancreas is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Irinotecan liposome injection for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is 18 years of age or older; **AND**

Universal Criteria

- Patient does not have bowel obstruction; **AND**

Pancreatic Adenocarcinoma

- Must be used in combination with fluorouracil and leucovorin; **AND**
  - Patient has locally advanced or metastatic disease; **AND**
    - Used after disease progression with one of the following:
      - Fluoropyrimidine (5-FU or capecitabine) based therapy without irinotecan; **OR**
      - Gemcitabine-based therapy; **OR**
  - Patient has local or metastatic disease recurrent post-resection; **AND**
    - Patient completed primary therapy < 6 months ago; **AND**
      - Patient previously received one of the following:
      - Fluoropyrimidine (5-FU or capecitabine) based therapy without irinotecan; **OR**
      - Gemcitabine-based therapy; **OR**
    - Patient completed primary therapy ≥ 6 months ago

RENEWAL CRITERIA

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in the Initial Approval Criteria; **AND**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe diarrhea, severe neutropenia, pulmonary toxicity (interstitial lung disease), severe hypersensitivity reactions, etc.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Pancreatic Cancer	Administer 70 mg/m², intravenously, every 14 days Note: Patients homozygous for UGT1A1*28: Administer 50 mg/m² every 14 days, and may titrate up to 70 mg/m², as tolerated in subsequent cycles.

LENGTH OF AUTHORIZATION

Coverage will be provided for 6 months and may be renewed.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- 172 billable units per 14 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Onivyde [package insert]. Cambridge, MA; Merrimack Pharmaceuticals, Inc.; June 2017. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) irinotecan liposomal. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
3. Wang-Gillam A, Li CP, Bodky G, NAPOLI-1 study group. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. Lancet. 2016 Feb 6;387(10018):545-557. doi: 10.1016/S0140-6736(15)00986-1. Epub 2015 Nov 29.
4. Lexi-Comp Online. (2021, February). AHFS DI. *Irinotecan*. Retrieved April 9, 2021 from Lexi-Comp Online with AHFS.
5. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2021, March). *Irinotecan liposome*. Retrieved April 9, 2021 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

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