Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 138.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Onivyde (irinotecan liposome injection)

I. Policy:
Onivyde (irinotecan liposome injection)

II. Purpose/Objective:
To provide a policy of coverage regarding Onivyde (irinotecan liposome injection)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Onivyde (irinotecan liposome injection) is a topoisomerase inhibitor 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.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Onivyde (irinotecan liposome injection) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Must be prescribed by an oncologist **AND**
- Medical record documentation of the patient being ≥18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic adenocarcinoma of the pancreas **AND**
- One of the following:
    - Medical record documentation that Onivyde is being prescribed in combination with fluorouracil and leucovorin **AND**
    - Medical record documentation of disease progression following gemcitabine-based therapy

  OR
    - Medical record documentation that Onivyde is being prescribed in combination with oxaliplatin, fluorouracil and leucovorin for first line treatment.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Onivyde [Prescribing Information]. Cambridge MA. Ipsen Biopharmaceuticals, Inc. February 2024.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 1/19/2016

Revised: 6/23/22 (Medicaid PARP statement), 6/6/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added), 6/19/24 (combo w/ FOLFOX, references)

Reviewed: 10/28/16, 9/29/17, 8/30/18, 8/29/19, 8/26/20, 7/26/21

MA UM Committee approval: 12/31/23, 8/30/24