

POLICIES AND PROCEDURE MANUAL

Policy: MBP 50.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Vectibix (panitumumab)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Vectibix (panitumumab)

II. Purpose/Objective:

To provide a policy of coverage regarding Vectibix (panitumumab)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

- 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 the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. 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

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid Business Segment

<u>Medically Necessary</u> — 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:

Vectibix (panitumumab) is a recombinant, human IgG2 kappa monoclonal antibody that binds specifically to the human Epidermal Growth Factor Receptor (EGFR). Overexpression of EGFR is detected in many human cancers, including those of the colon and rectum. When Vectibix binds to EGFR it inhibits the binding of ligands for EGFR. This results in inhibition of cell growth, induction of apoptosis, decreased pro-inflammatory cytokine and vascular growth factor production.

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

Vectibix (panitumumab) will be considered medically necessary for all lines of business when all of the following criteria are met:

1. Metastatic Colorectal Cancer, RAS wild-type

- Prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of metastatic colorectal carcinoma AND
 - Used in combination with fluorouracil, leucovorin, and oxaliplatin (FOLFOX) for first line treatment OR
 - Used as monotherapy following disease progression on (or intolerance or contraindication to) fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy regimens AND
- Medical record documentation of wild-type RAS (defined as wild-type (negative) in both KRAS and NRAS as
 determined by an FDA-approved test for this use)

2. Metastatic Colorectal Cancer, KRAS G12C-mutated

- Medical record documentation that Vectibix is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of metastatic colorectal carcinoma AND
- Medical record documentation of KRAS G12C mutation, as determined by a Food and Drug Administration (FDA)-approved test AND
- Medical record documentation of prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy AND
- Medical record documentation that Vectibix is being prescribed in combination with Lumakras (sotorasib)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 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.

LIMITATIONS: Vectibix is not indicated for the treatment of patients with RAS-mutant metastatic colorectal cancer (unless used in combination with sotorasib in *KRAS* G12C-mutated mCRC) or for whom RAS mutation status is unknown

<u>Note</u>: 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. Vectibix [prescribing information]. Thousand Oaks, CA: Amgen Inc; January 2025.

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

Devised: 1/10/07

Revised: 8/09 (added KRAS requirement), 3/24/15 (formatting, addition of criteria, added authorization duration), 9/19/17 (criteria updated), 8/18/22 (defined FOLFOX, Medicaid PARP statement), 8/9/23 (LOB carve out, Medicaid business segment), 12/31/23 (references added), 4/18/25 (mCRC KRAS, LOB table, taglines)

Reviewed: 8/10, 8/11, 2/12; 3/24/15, 3/16, 1/31/17, 8/30/18, 8/29/19, 8/26/20, 8/19/21, 7/26/24

MA UM Committee approval: 12/31/23, 12/31/24, 7/14/25

DHS PARP approval: 5/16/25

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