

**Policy: MBP 50.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Vectibix (panitumumab)**

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### **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**

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:**

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**

- Prescribed by a hematologist or oncologist **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)

**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 or for whom RAS mutation status is unknown

Note: Vectibix is not effective for the treatment of patients with RAS-mutant mCRC (defined as a RAS mutation in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), or exon 4 (codons 117 and 146) of *KRAS* and *NRAS*).

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.**

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)

**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