# Panitumumab (Vectibix®)

## 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 or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

## POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Vectibix is indicated for the treatment of patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):
1. As first-line therapy in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin).
2. As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

Limitation of Use: Vectibix is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

B. Compendial Use
Colorectal cancer

All other indications are considered experimental/investigational and not medically necessary.

### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of *RAS* wild-type status or KRAS G12C mutation, where applicable.
B. Documentation of *BRAF* mutation status, where applicable.

### III. CRITERIA FOR INITIAL APPROVAL

**Colorectal Cancer (CRC)**
Authorization of 6 months may be granted for the treatment of colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, for unresectable/inoperable, advanced, or metastatic disease and the member has not previously experienced clinical failure on cetuximab when either of the following criteria are met:
1. The member meets all of the following criteria:
    i. The *RAS (KRAS and NRAS)* mutation status is negative (wild-type)

ii. If the tumor is positive for BRAF V600E mutation, the requested medication will be used in combination with encorafenib (Braftovi)
iii. For colon cancer, the tumor is left-sided only, or

2. The member meets all of the following criteria:
   i. The disease is KRAS G12C mutation positive
   ii. The requested medication will be used in combination with sotorasib (Lumakras) or adagrasib (Krazati)
   iii. The member previously received treatment with chemotherapy

## IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## 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.

## 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).

## REFERENCES

1. Vectibix [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 22, 2023.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer. Version 3.2023. Accessed September 22, 2023. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 3.2023. Accessed September 22, 2023. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf

**EFFECTIVE DATE** 5/31/2024

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