

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Injectable) – Vectibix Prior Authorization Policy

- Vectibix® (panitumumab intravenous infusion – Amgen)

**REVIEW DATE:** 07/27/2022; selected revision 08/24/2022

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### OVERVIEW

Vectibix, an epidermal growth factor receptor monoclonal antibody, is indicated for the treatment of 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) as:<sup>1</sup>

- First-line therapy in combination with FOLFOX (5-fluorouracil [5-FU], leucovorin, oxaliplatin).
- Monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

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

### Guidelines

The National Comprehensive Cancer Network (NCCN) **Colon Cancer** guidelines (version 1.2022 – February 25, 2022) recommend Vectibix as primary therapy for unresectable, advanced, or metastatic *KRAS/NRAS/BRAF* wild-type gene and left-sided tumors only in combination with irinotecan, FOLFOX, FOLFIRI (5-FU, leucovorin, irinotecan), or FOLFOXIRI (5-FU, leucovorin, oxaliplatin, irinotecan) regimens in patients who can tolerate intensive therapy or as a single agent in patients who cannot tolerate intensive therapy.<sup>2,4</sup> Reference to left-sided only disease refers to a primary tumor that originated in the left side of the colon. Therapies recommended after first progression vary depending on the initial treatment regimen (i.e., 5-FU/leucovorin-based or capecitabine-based therapy) that was used. The NCCN guidelines recommend Vectibix, in combination with irinotecan, FOLFOX, or FOLFIRI for the subsequent treatment of *KRAS/NRAS/BRAF* wild-type tumors; or in combination with Braftovi® (encorafenib capsules) for the subsequent treatment of *BRAF V600E* positive disease. The NCCN **Rectal Cancer** guidelines (version 1.2022 – February 25, 2022) make the same recommendations for Vectibix for the treatment of rectal cancer.<sup>3,4</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vectibix. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vectibix as well as the monitoring required for adverse events and long-term efficacy, approval requires Vectibix to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vectibix is recommended in those who meet the following criteria:

### FDA-Approved Indication

07/27/2022

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1. **Colon and Rectal Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
  - A) Patient has advanced or metastatic disease; AND
  - B) Patient’s tumor or metastases are wild-type *RAS* (*KRAS* wild-type and *NRAS* wild-type) [that is, the tumor or metastases are *KRAS* and *NRAS* mutation negative]; AND
  - C) The primary tumor originated on the left side of the colon (from splenic flexure to rectum); AND
  - D) Patient meets ONE of the following criteria (i or ii):
    - i. Patient’s tumor or metastases are wild-type *BRAF* (that is, the tumor or metastases are *BRAF V600E* mutation negative); OR
    - ii. Patient’s tumor or metastases are *BRAF V600E* mutation-positive and the patient meets the following (a and b):
      - a) Patient has previously received a chemotherapy regimen for colon or rectal cancer; AND  
Note: Examples of chemotherapy regimens include a fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine, oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin).
      - b) Vectibix is prescribed in combination with Braftovi (encorafenib capsules); AND
  - E) Vectibix is prescribed by or in consultation with an oncologist.

#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vectibix is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### REFERENCES

1. Vectibix® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; August 2021.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – February 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 16, 2022.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – February 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 16, 2022.
4. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 16, 2022. Search term: panitumumab.