# Medical Policy:

## Vectibix (panitumumab) Intravenous

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.110 | February 6, 2024 | January 1, 2020 |



## Definitions

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

## Length of Authorization

Coverage will be provided for 12 months and may be renewed.

## Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

- 70 units every 14 days

## Guideline

I. **Initial Approval Criteria**

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**

1. **Colon and Rectal Cancer†.**
   A. Patient has not been previously treated with cetuximab or panitumumab; **AND**
   B. Will not be used as part of an adjuvant treatment regimen; **AND**
      i. Patient has both KRAS and NRAS mutation negative (wild-type) and BRAF V600E negative (wild-type) disease as determined by an FDA or CLIA-compliant test; **AND**
         a. Used as primary treatment for metastatic or unresectable (or medically inoperable) disease; **AND**
            (1) Used in combination with FOLFOX †; **OR**
            (2) Used in combination with CapeOX or FOLFIRI §; **AND**
               a) Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
               b) Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
                  -Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**
            (3) Used in combination with irinotecan §; **AND**
               a) Patient previously received FOLFOX or CapeOX within the past 12 months; **AND**
               b) Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
         b. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any rectal cancer; **AND**
            (1) Used in combination with CapeOX, FOLFOX, or FOLFIRI; **AND**
               a) Used if resection is contraindicated following total neoadjuvant therapy; **AND**
                  - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
                  - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
                  ♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**
               b) Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **AND**
                  -Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; **OR**
         c. Used as subsequent therapy for advanced or metastatic disease; **AND**
            (1) Used as a single agent; **AND**
               a) Patient has fluoropyrimidine-, oxaliplatin-, and irinotecan-refractory disease †; **OR**
               b) Patient has irinotecan-intolerant disease §; **AND**
                  - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**

- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**

♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**

(2) Used in combination with irinotecan §; **AND**

a) Patient has oxaliplatin-refractory disease, irinotecan-refractory disease,or oxaliplatin- and irinotecan-refractory disease; **AND**

- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**

- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**

♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**

(3) Used in combination with FOLFIRI §; **AND**

a) Patient has oxaliplatin-refractory disease**; **AND**

- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**

- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**

♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**

(4) Used in combination with FOLFOX or CapeOx §; **AND**

a)Patient has irinotecan-refractory disease**; **AND**

- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**

- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**

♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy

**§**Colon cancer patients must have left-sided tumors only.

**May also be used for progression on non-intensive therapy in patients with improvement in functional status (except if received previous fluoropyrimidine).

**†** FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); Φ Orphan Drug

II. **Renewal Criteria**

Coverage can be renewed based upon the following criteria:

1. Patient continues to meet criteria identified above; **AND**
2. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: dermatologic/soft-tissue toxicity, electrolyte depletion, severe infusion related reactions, acute renal failure, pulmonary fibrosis/interstitial lung disease (ILD), keratitis, etc.

**Limitations/Exclusions**

Vectibix is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J9303 | Injection, panitumumab, 10 mg; 1 billable unit = 10 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 55513-0954-xx | Vectibix 100 mg/5 mL solution for injection |
| 55513-0956-xx | Vectibix 400 mg/20 mL solution for injection |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| C17.0 | Malignant neoplasm duodenum |
| C17.1 | Malignant neoplasm jejunum |
| C17.2 | Malignant neoplasm ileum |
| C17.8 | Malignant neoplasm of overlapping sites of small intestines |
| C17.9 | Malignant neoplasm of small intestine, unspecified |
| C18.0 | Malignant neoplasm of cecum |
| C18.1 | Malignant neoplasm of appendix |
| C18.2 | Malignant neoplasm of ascending colon |
| C18.3 | Malignant neoplasm of hepatic flexure |
| C18.4 | Malignant neoplasm of transverse colon |
| C18.5 | Malignant neoplasm of splenic flexure |
| C18.6 | Malignant neoplasm of descending colon |
| C18.7 | Malignant neoplasm of sigmoid colon |
| C18.8 | Malignant neoplasm of overlapping sites of large intestines |
| C18.9 | Malignant neoplasm of colon, unspecified |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C78.00 | Secondary malignant neoplasm of unspecified lung |
| C78.01 | Secondary malignant neoplasm of right lung |
| C78.02 | Secondary malignant neoplasm of left lung |
| C78.6 | Secondary malignant neoplasm of retroperitoneum and peritoneum |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.068 | Personal history of other malignant neoplasm of small intestine |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 2/6/2025 | Annual Review: Initial Criteria: removed the following (some may have been reworded or added back to the new criteria) "Patient has unresectable, advanced or metastatic disease; **AND** 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** The primary tumor originated on the left side of the colon (from splenic flexure to rectum); **AND** Patient meets **ONE** of the following criteria (i or ii): Patient's tumor or metastases are wild-type *BRAF* (that is, the tumor or metastases are *BRAF V600E* mutation-negative); **OR** Patient's tumor or metastases are *BRAF V600E* mutation-positive and the patient meets the following (a **and** b): Patient has previously received a chemotherapy regimen for colon or rectal cancer; **AND** *Note: Examples of chemotherapy regimens include 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).* Vectibix is prescribed in combination with Braftovi (encorafenib capsules); **AND** Vectibix is prescribed by, or in consultation, with an oncologist." Updated the initial criteria as follows: "A. Patient has not been previously treated with cetuximab or panitumumab; AND<br>B. Will not be used as part of an adjuvant treatment regimen; AND<br>i. Patient has both KRAS and NRAS mutation negative (wild-type) and BRAF V600E negative (wild-type) disease as determined by an FDA or CLIA-compliant test; AND<br>a. Used as primary treatment for metastatic or unresectable (or medically inoperable) disease; AND<br>(1) Used in combination with FOLFOX †; OR<br>(2) Used in combination with CapeOX or FOLFIRI §; AND<br>a) Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR<br>b) Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND<br>-Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR<br>(3) Used in combination with irinotecan §; AND<br>a) Patient previously received FOLFOX or CapeOX within the past 12 months; AND<br>b) Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR<br>b. Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any rectal cancer; AND<br>(1) Used in combination with CapeOX, FOLFOX, or FOLFIRI; AND<br>a) Used if resection is contraindicated following total neoadjuvant therapy; AND<br>- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR<br>- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND<br>♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR<br>b) Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; AND<br>-Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR<br>c. Used as subsequent therapy for advanced or metastatic disease; AND<br>(1) Used as a single agent; AND<br>a) Patient has fluoropyrimidine-, oxaliplatin-, and irinotecan-refractory disease †; OR |

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|---|---|---|
| | | b) Patient has irinotecan-intolerant disease §; AND<br>- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR<br>- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND<br>♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR<br>(2) Used in combination with irinotecan §; AND<br>a) Patient has oxaliplatin-refractory disease, irinotecan-refractory disease,or oxaliplatin- and irinotecan-refractory disease; AND<br>- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR<br>- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND<br>♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR<br>(3) Used in combination with FOLFIRI §; AND<br>a) Patient has oxaliplatin-refractory disease**; AND<br>- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR<br>- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND<br>♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR<br>(4) Used in combination with FOLFOX or CapeOx §; AND<br>a)Patient has irinotecan-refractory disease**; AND<br>- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR<br>- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND<br>♦ Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy |
| EmblemHealth & ConnectiCare | 1/2/2024 | Annual Review:<br>Initial Criteria: Added: " unresectable" to the statement: "Patient has unresectable, advanced or metastatic disease; **AND"** |
| EmblemHealth & ConnectiCare | 4/11/2023 | Annual Review: increased length of authorization from 6 months to 12 months; Removed under Colorectal Cancer:<br>A. Patient has 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; AND<br>B. Will not be used as part of an adjuvant treatment regimen; AND<br>C. Patient has not been previously treated with cetuximab or panitumumab; AND<br>i. Patient must have progressive, metastatic disease; AND<br>a. Used as single agent therapy after failure with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy †; OR<br>ii. Patient must have metastatic, or unresectable advanced disease; AND<br>a. Used in combination with irinotecan- or oxaliplatin-based regimens; OR<br>b. Used in combination with vemurafenib based regimen in patients with BRAF V600E mutations.<br>Added under Colon and Rectal Cancer:<br>A. Patient has advanced or metastatic disease; **AND**<br>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** |

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|---|---|---|
| | | C. The primary tumor originated on the left side of the colon (from splenic flexure to rectum); **AND**<br>D. Patient meets **ONE** of the following criteria (i or ii):<br>i. Patient's tumor or metastases are wild-type *BRAF* (that is, the tumor or metastases are *BRAF V600E* mutation-negative); **OR**<br>ii. Patient's tumor or metastases are *BRAF V600E* mutation-positive and the patient meets the following (a **and** b):<br>c) Patient has previously received a chemotherapy regimen for colon or rectal cancer; **AND**<br>*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).*<br>d) Vectibix is prescribed in combination with Braftovi (encorafenib capsules); **AND**<br>E. Vectibix is prescribed by or in consultation with an oncologist. |
| EmblemHealth & ConnectiCare | 1/17/2023 | Transfer to New Template |
| EmblemHealth & ConnectiCare | 1/1/2020 | Annual Review |

## References


1. Vectibix [package insert]. Thousand Oaks, CA; Amgen, Inc; June 2017. Accessed Demeber 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) panitumumab. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2018.