Medical Policy:

Vectibix (panitumumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.110	January 2, 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†.** Approve if the patient meets the following criteria (A, B, C, D, and E):
   A. Patient has unresectable, 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.

† FDA-labeled indication(s); **‡** Compendia Recommended Indication(s)

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	1/2/2024	Annual Review: 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: 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 B. Will not be used as part of an adjuvant treatment regimen; AND C. Patient has not been previously treated with cetuximab or

		panitumumab; AND i. Patient must have progressive, metastatic disease; AND a. Used as single agent therapy after failure with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy †; OR ii. Patient must have metastatic, or unresectable advanced disease; AND a. Used in combination with irinotecan- or oxaliplatin-based regimens; OR b. Used in combination with vemurafenib based regimen in patients with BRAF V600E mutations. Added under Colon and Rectal Cancer: 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): iii. Patient's tumor or metastases are wild-type *BRAF* (that is, the tumor or metastases are *BRAF V600E* mutation-negative); **OR** iv. Patient's tumor or metastases are *BRAF V600E* mutation-positive and the patient meets the following (a **and** b): c. 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).* d. Vectibix is prescribed in combination with Braftovi (encorafenib capsules); **AND** 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.