

Medical Policy:

Vectibix (panitumumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.110	January 2, 2024	January 1, 2020

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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
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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

		<p>panitumumab; AND</p> <p>i. Patient must have progressive, metastatic disease; AND</p> <p>a. Used as single agent therapy after failure with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy †; OR</p> <p>ii. Patient must have metastatic, or unresectable advanced disease; AND</p> <p>a. Used in combination with irinotecan- or oxaliplatin-based regimens; OR</p> <p>b. Used in combination with vemurafenib based regimen in patients with BRAF V600E mutations.</p> <p>Added under Colon and Rectal Cancer:</p> <p>A. Patient has advanced or metastatic disease; AND</p> <p>B. Patient’s tumor or metastases are wild-type <i>RAS</i> (<i>KRAS</i> wild-type and <i>NRAS</i> wild-type) [that is, the tumor or metastases are <i>KRAS</i> and <i>NRAS</i> mutation negative]; AND</p> <p>C. The primary tumor originated on the left side of the colon (from splenic flexure to rectum); AND</p> <p>D. Patient meets ONE of the following criteria (i <u>or</u> ii):</p> <p>iii. Patient’s tumor or metastases are wild-type <i>BRAF</i> (that is, the tumor or metastases are <i>BRAF V600E</i> mutation-negative); OR</p> <p>iv. Patient’s tumor or metastases are <i>BRAF V600E</i> mutation-positive and the patient meets the following (a and b):</p> <p>c. Patient has previously received a chemotherapy regimen for colon or rectal cancer; AND</p> <p><i>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).</i></p> <p>d. Vectibix is prescribed in combination with Braftovi (encorafenib capsules); AND</p> <p>E. Vectibix is prescribed by or in consultation with an oncologist.</p>
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.