Vectibix® (panitumumab)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

– 70 billable units every 14 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Colorectal Cancer † ‡ ¥ [1,2,6-8,10,11-13,3e,5e,8e,11e,13e-15e]

- Patient has not been previously treated with cetuximab or panitumumab; **AND**
- Will not be used as part of an adjuvant treatment regimen; **AND**
- Will not be used in combination with an anti-VEGF agent (e.g., bevacizumab, ramucirumab); **AND**
    - 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**

        - Use of panitumumab will be restricted to patients who are not a candidate for cetuximab; **AND**

- Used as primary treatment for metastatic or unresectable (or medically inoperable) disease §; **AND**
  - Used in combination with FOLFOX †; **OR**
  - Used in combination with CapeOX or FOLFIRI; **OR**
  - Used in combination with irinotecan; **AND**
    - Patient previously received FOLFOX or CapeOX within the past 12 months; **OR**
- Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or locally unresectable or medically inoperable rectal cancer; **AND**
  - Used in combination with CapeOX, FOLFOX, or FOLFIRI; **AND**
    - Used if resection is contraindicated following total neoadjuvant therapy; **OR**
    - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **OR**
- Used for progression on non-intensive therapy, except if received previous fluoropyrimidine, with improvement in functional status §; **AND**
  - Used in combination with FOLFOX, CapeOX, or FOLFIRI; **OR**
- Used as subsequent therapy for advanced or metastatic disease; **AND**
  - Used as a single agent; **AND**
    - Patient has fluoropyrimidine-, oxaliplatin-, and irinotecan-refractory disease †; **OR**
    - Patient has irinotecan-intolerant disease; **OR**
  - Used in combination with irinotecan; **AND**
    - Patient has oxaliplatin-refractory disease, irinotecan-refractory disease, or oxaliplatin- and irinotecan-refractory disease; **OR**
    - Patient has disease that is refractory to therapy without irinotecan or oxaliplatin; **OR**
  - Used in combination with FOLFIRI; **AND**
    - Patient has oxaliplatin-refractory disease; **OR**
    - Patient has disease refractory to therapy without irinotecan or oxaliplatin; **OR**

- Patient has KRAS G12C mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖ † ‡; **AND**
  - Used as initial treatment for unresectable metastatic disease after previous FOLFOX or CapeOx within the past 12 months; **AND**
    - Used in combination with sotorasib; **OR**

- Used as subsequent therapy; **AND**
  - Used for progression of advanced or metastatic disease; **AND**
  - Used in combination with sotorasib; **AND**
  - Patient has received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, unless not a candidate

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

¥ *Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed patients. If deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB>50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the patient is a candidate.*

Appendiceal Adenocarcinoma – Colon Cancer ¥ ‡ [2,6,12]

- Patient has KRAS G12C mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used in combination with sotorasib; **AND**
  - Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
  - Patient has received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, unless not a candidate

¥ *Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed patients. If deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB>50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the patient is a candidate.*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

❖*If confirmed using an FDA approved assay – http://www.fda.gov/companiondiagnostics*

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

IV. Renewal Criteria [1,6,11]

Prior authorization validity may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by a stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: dermatologic/soft-tissue toxicity, electrolyte depletion, severe infusion-related reactions, acute renal failure, pulmonary fibrosis/interstitial lung disease (ILD), photosensitivity, ocular toxicities (i.e., keratitis, corneal perforation), etc.

V. Dosage/Administration [1,6,11-12]

Indication	Dose
All indications	Administer 6 mg/kg intravenously every 14 days until disease progression or unacceptable toxicity. *Note: When administered with sotorasib for KRAS G12C-mutated CRC, treatment may be continued until disease progression, unacceptable toxicity, or until sotorasib is withheld or discontinued.*

VI. Billing Code/Availability Information

HCPCS Code:

- J9303 – Injection, panitumumab, 10 mg; 1 billable unit = 10 mg

NDC(s):

- Vectibix 100 mg/5 mL single-dose vial, solution for injection: 55513-0954-xx
- Vectibix 400 mg/20 mL single-dose vial, solution for injection: 55513-0956-xx

VII. References (STANDARD)

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2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) panitumumab. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE

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11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Rectal Cancer. Version 2.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.
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VIII. References (ENHANCED)

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD,

or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC