Vectibix® (panitumumab)
(Intravenous)

-E-

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Vectibix 100 mg/5 mL solution for injection single-dose vial: 3 vials every 14 days
- Vectibix 400 mg/20 mL solution for injection single-dose vial: 2 vials every 14 days

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

- 70 billable units every 14 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

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

Colorectal Cancer † ‡ [1,2,6-8,10,11-12,3e,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**
        - 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; **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**

– Used in combination with irinotecan; **AND**
  - Patient previously received FOLFOX or CapeOX within the past 12 months; **AND**
  - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**

▪ Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any <u>rectal</u> cancer; **AND**

– Used in combination with CapeOX, FOLFOX, or FOLFIRI; **AND**
  - 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**
  - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **AND**
    - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; **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 §; **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**

– Used in combination with irinotecan **§**; **AND**
  - 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**

– Used in combination with FOLFIRI **§**; **AND**
  - Patient has oxaliplatin-refractory disease******; **AND**
    - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
    - Patient has mismatch repair deficient/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).*

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.

❖*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]

Coverage 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
Colorectal Cancer	Administer 6 mg/kg intravenously every 14 days until disease progression or unacceptable toxicity.

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)

1. Vectibix [package insert]. Thousand Oaks, CA; Amgen, Inc; August 2021. Accessed February 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) panitumumab. National Comprehensive Cancer Network, 2024. 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 February 2024.
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5. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. BMJ. 2016 Feb 29;352:i788.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Colon Cancer Version 1.2024. National Comprehensive Cancer Network, 2024. 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 NCCN Guidelines, go online to NCCN.org. Accessed February 2024.
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11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Rectal Cancer. Version 1.2024. National Comprehensive Cancer Network, 2024. 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 February 2024.
12. Kuboki Y, Yaeger R, Fakih MG, et al. Sotorasib in combination with panitumumab in refractory KRAS G12C-mutated colorectal cancer: Safety and efficacy for phase Ib full expansion cohort. Ann Oncol 2022;33:S136-S196

VIII. References (ENHANCED)

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4e. Van Cutsem E, Köhne CH, Láng I, et al. Cetuximab Plus Irinotecan, Fluorouracil, and Leucovorin As First-Line Treatment for Metastatic Colorectal Cancer: Updated Analysis of Overall Survival According to Tumor KRAS and BRAF Mutation Status. Journal of Clinical Oncology 2011 29:15, 2011-2019.

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C18.0	Malignant neoplasm of cecum
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	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC