Vectibix® (panitumumab)
(Intravenous)

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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: 1 vial 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**

Universal Criteria [1,2]

- Patient is both KRAS and NRAS mutation negative (wild-type) as determined by an FDA or CLIA-compliant test❖; **AND**
- Patient has not been previously treated with cetuximab or panitumumab; **AND**
- Will not be used as part of an adjuvant treatment regimen; **AND**

Colorectal Cancer † [1,2,6,11]

- Patient has metastatic, unresectable (or medically inoperable), or advanced disease that is BRAF mutation negative (wild-type); **AND**
  - Used as primary treatment; **AND**
    - Used in combination with FOLFOX †; **OR**

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- Used in combination with CapeOX or FOLFIRI §; **AND**
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**
- Used in combination with an irinotecan-based regimen after previous FOLFOX or CapeOX within the past 12 months §; **AND**
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for immunotherapy *(Note: Only applies to Colon Cancer)*; **OR**
- Used as a single agent for <u>rectal</u> cancer if resection is contraindicated following neoadjuvant therapy; **AND**
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**

o Used as subsequent therapy; **AND**

- Used as a single agent for fluoropyrimidine-, oxaliplatin-, and irinotecan-refractory disease †; **OR**
- Used in combination with irinotecan for oxaliplatin-refractory disease, irinotecan-refractory disease, or oxaliplatin- and irinotecan-refractory disease §; **AND**
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**
- Used in combination with FOLFIRI for oxaliplatin-refractory disease §**; **AND**
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**

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        - Used in combination with FOLFOX or CapeOx for irinotecan-refractory disease §**; **AND**
            - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
            - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**
        - Used as a single agent for irinotecan-intolerant disease; **AND**
            - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
            - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; **OR**
- Patient has BRAF V600E mutation positive disease as determined by an FDA or CLIA-compliant test❖‡; **AND**
    - Used in combination with encorafenib; **AND**
        - Used as initial treatment for unresectable metastatic disease after previous FOLFOX or CapeOX within the past 12 months; **AND**
            - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
            - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND is not a candidate for immunotherapy *(Note: Only applies to Colon Cancer)*; **OR**
        - Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; **AND**
            - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
            - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease AND 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).*

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

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

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IV. Renewal Criteria [1,6,11]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other 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]

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

1. Vectibix [package insert]. Thousand Oaks, CA; Amgen, Inc; August 2021. Accessed May 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) panitumumab. National Comprehensive Cancer Network, 2023. 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 May 2023.

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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 Drugs & Biologics Compendium (NCCN Compendium®) Colon Cancer. Version 2.2023. National Comprehensive Cancer Network, 2023. 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 May 2023.
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10. Douillard JY, Siena S, Cassidy J, et al. Final results from PRIME: randomized phase III study of panitumumab with FOLFOX4 for first-line treatment of metastatic colorectal cancer. Ann Oncol. 2014 Jul;25(7):1346-55. doi: 10.1093/annonc/mdu141. Epub 2014 Apr 8.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Rectal Cancer. Version 2.2023. National Comprehensive Cancer Network, 2023. 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 May 2023.

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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)

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 Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

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

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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