

## 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: 3 vials every 14 days
- Vectibix 400 mg/20 mL solution for injection: 1 vial every 14 days

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

- 70 units every 14 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

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

#### Universal Criteria <sup>1,2</sup>

- Patient is both KRAS and NRAS mutation negative (wild-type) as determined by an FDA or CLIA-compliant test<sup>3</sup>; **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 † <sup>1,2,6-8,10,11,3e,5e,8e,11e,13e-15e</sup>

- Will not be used in combination with an anti-VEGF agent (e.g., bevacizumab, ramucirumab); **AND**
- Patient has metastatic, unresectable (or medically inoperable), or advanced disease that is BRAF mutation negative (wild-type); **AND**
  - Used as first-line treatment §; **AND**
    - Used in one of the following:

- Used in combination with FOLFOX †
- Used in combination with FOLFIRI
- Used in combination with an irinotecan-based regimen after previous adjuvant FOLFOX or CapeOX within the past 12 months; **AND**

- Use of panitumumab as first-line treatment will be restricted to patients with a contraindication or intolerance to cetuximab; **OR**

- Used as subsequent therapy; **AND**

- Used in one of the following:
  - Used as single agent therapy after failure with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy †
  - Used in combination with irinotecan for oxaliplatin- and/or irinotecan-refractory disease §
  - Used in combination with FOLFIRI for oxaliplatin-refractory disease §\*\*; **AND**

As single agent therapy:

- Use of panitumumab as subsequent therapy will be restricted to patients with a contraindication or intolerance to cetuximab

In combination with irinotecan for oxaliplatin-refractory disease ONLY:

- Patient must demonstrate an inadequate response to bevacizumab (*or a commercially available bevacizumab biosimilar agent*) in combination with irinotecan, unless there is a contraindication or intolerance, prior to approval of panitumumab; **AND**
- Use of panitumumab as subsequent therapy will be restricted to patients with a contraindication or intolerance to cetuximab

In combination with FOLFIRI:

- Use of panitumumab will be restricted to patients with a contraindication or intolerance to bevacizumab (*or a commercially available bevacizumab biosimilar agent*) in combination with FOLFIRI; **AND**
- Use of panitumumab as subsequent therapy will be restricted to patients with a contraindication or intolerance to cetuximab

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

\*\**May also be used for progression on non-intensive therapy, except if received previous fluoropyrimidine with improvement in functional status (Note: Colon cancer patients must have left-sided tumors only AND step therapy for bevacizumab does not apply).*

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-labeled indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

#### IV. Renewal Criteria <sup>1,6,11</sup>

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 <sup>1,6,11</sup>

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

#### VI. Billing Code/Availability Information

HCPSC 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, 2022. The NCCN

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6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Colon Cancer Version 1.2022. National Comprehensive Cancer Network, 2022. 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 June 2022.
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11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Rectal Cancer. Version 1.2022. National Comprehensive Cancer Network, 2022. 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 June 2022.

## VIII. References (ENHANCED)

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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 Determinations (LCDs), and Local Coverage Articles (LCAs) 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/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, 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