

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) [Pharmacy Benefit]:

- Vectibix 100 mg/5 mL solution for injection: 7 vials every 14 days
- Vectibix 400 mg/20 mL solution for injection: 2 vials every 14 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 70 units every 14 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**

Colorectal Cancer †

- Patient is both KRAS and NRAS mutation negative (wild-type) as determined by FDA-approved test*; **AND**
- Will not be used as part of an adjuvant treatment regimen; **AND**
- Patient has not been previously treated with cetuximab or panitumumab; **AND**
 - Patient must have progressive, metastatic disease; **AND**
 - Used as single agent therapy after failure with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy ‡; **OR**
 - Patient must have metastatic, or unresectable advanced disease; **AND**
 - Used in combination with irinotecan- or oxaliplatin-based regimens; **OR**

- Used in combination with a vemurafenib and irinotecan in patients with BRAF V600E mutation positive disease; **AND**
 - Used as primary therapy after previous adjuvant FOLFOX or CapeOX within the past 12 months; **OR**
 - Used as subsequent therapy for disease progression after previous treatment with fluoropyrimidine-, oxaliplatin-, or irinotecan-based therapy

*<http://www.fda.gov/companiondiagnostics>

† FDA-labeled indication(s); ‡ Compendia Recommended Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Tumor response with 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 the following: dermatologic/soft-tissue toxicity, electrolyte depletion, severe infusion-related reactions, acute renal failure, pulmonary fibrosis/interstitial lung disease (ILD), keratitis, etc.

V. Dosage/Administration

| Indication | Dose |
|-----------------|-------------------------------------|
| All indications | 6 mg/kg intravenously every 14 days |

VI. Billing Code/Availability Information

JCode:

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

NDC(s):

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

VII. References

1. Vectibix [package insert]. Thousand Oaks, CA; Amgen, Inc; June 2017. Accessed October 2018.
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 October 2018.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 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 |

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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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): 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 |