

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: 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) [HCPCS Unit]:

- 70 units every 14 days

III. Initial Approval Criteria ^{1,2,6-10}

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 advanced disease that is BRAF mutation negative (wild-type); **AND**
 - Used as first-line or primary therapy; **AND**

- Used in combination with FOLFOX †; **OR**
- Used in combination with FOLFIRI (*Note: For colon cancer patients with left-sided tumors only*); **OR**
- Used in combination with an irinotecan-based regimen after previous adjuvant FOLFOX or CapeOX within the past 12 months (*Note: For colon cancer patients with left-sided tumors only*); **OR**
- Used as subsequent therapy; **AND**
 - Used as single agent therapy after failure with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy †; **OR**
 - Used as a single agent for oxaliplatin- and irinotecan-refractory disease OR irinotecan-intolerant disease; **OR**
 - Used in combination with irinotecan for oxaliplatin- and/or irinotecan-refractory disease; **OR**
 - Used in combination with FOLFIRI for oxaliplatin-refractory disease; **OR**
 - Used in combination with FOLFOX for irinotecan-refractory disease; **OR**
- Used in combination with FOLFOX or FOLFIRI for one of the following (*Note: For colon cancer patients with left-sided tumors only*):
 - Unresectable metastatic disease that remains unresectable after primary systemic therapy; **OR**
 - Unresectable metastatic disease in patients who have received adjuvant FOLFOX or CapeOX more than 12 months ago OR who have received previous fluorouracil/leucovorin (5-FU/LV) or capecitabine therapy; **OR**
 - Disease progression on non-intensive therapy with improvement in functional status (*excluding patients previously treated with fluoropyrimidine*); **OR**
- Patient has progressive, metastatic, unresectable, or advanced disease that is BRAF V600E mutation positive; **AND**
 - Used in combination with encorafenib; **AND**
 - Used as subsequent therapy for disease progression after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
 - Used as primary treatment after previous adjuvant FOLFOX or CapeOX within the past 12 months

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

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

IV. Renewal Criteria^{1,2,6-10}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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, keratitis, etc.

V. Dosage/Administration ^{1,3-5}

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 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 July 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) panitumumab. National Comprehensive Cancer Network, 2020. 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 July 2020.
3. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. *J Oncol Pract.* 2018 Mar;14(3):e130-e136.
4. Hematology/Oncology Pharmacy Association (2019). *Intravenous Cancer Drug Waste Issue Brief*. Retrieved from http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf
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 4.2020. National Comprehensive Cancer Network, 2020. 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 July 2020.
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8. Price TJ, Peeters M, Kim TW, et al. Panitumumab versus cetuximab in patients with chemotherapy-refractory wild-type KRAS exon 2 metastatic colorectal cancer (ASPECCT): a randomised, multicentre, open-label, non-inferiority phase 3 study. *Lancet Oncol*. 2014 May;15(6):569-79. doi: 10.1016/S1470-2045(14)70118-4. Epub 2014 Apr 14.
9. Kim TW, Elme A, Kusic Z, et al. A phase 3 trial evaluating panitumumab plus best supportive care vs best supportive care in chemorefractory wild-type KRAS or RAS metastatic colorectal cancer. *Br J Cancer*. 2016 Nov 8;115(10):1206-1214. doi: 10.1038/bjc.2016.309. Epub 2016 Oct 13.
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 4.2020. National Comprehensive Cancer Network, 2020. 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 July 2020.

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), 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: <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/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)
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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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