# 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]

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 † [1,2,6-8,10,11,3e,5e,8e,11e,13e-15e]

- 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 or primary therapy *(Note: Colon cancer patients must have left sided tumors)*; **AND**
  - Used in one of the following:
    - Used in combination with FOLFOX; **OR**
    - Used in combination with FOLFIRI; **OR**
    - Used in combination with an irinotecan-based regimen after previous adjuvant FOLFOX or CapeOX within the past 12 months; **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 †; **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 or FOLFIRI for one of the following *(Note: Colon cancer patients must have left-sided tumors)*:
    - Disease that remains unresectable after primary systemic therapy; **OR**
    - Disease progression on non-intensive therapy with improvement in functional status *(excluding patients previously treated with fluoropyrimidine)*

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**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); Φ Orphan Drug

## 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 (STANDARD)


1. Vectibix [package insert]. Thousand Oaks, CA; Amgen, Inc; June 2017. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) panitumumab. National Comprehensive Cancer Network, 2021. 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 March 2021.
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6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Colon Cancer Version 2.2021. National Comprehensive Cancer Network, 2021. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and

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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.
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11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Rectal Cancer. Version 1.2021. National Comprehensive Cancer Network, 2021. 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 March 2021.

## VIII. References (ENHANCED)

1e. Douillard JY, Oliner KS, Siena S, et al. Panitumumab–FOLFOX4 Treatment and RAS Mutations in Colorectal Cancer. N Engl J Med 2013; 369:1023-1034.

2e. Hurwitz H, Fehrenbacher L, Novotny W, et al. Bevacizumab plus Irinotecan, Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer. N Engl J Med 2004; 350:2335-2342.

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

## Appendix 3 – CLINICAL LITERATURE REVIEW

OS = overall survival; PFS = progression-free survival; ORR = objective response rate; CR = complete response; PR = partial response; DoR = duration of response; TTP = time to progression; FFS = failure-free survival; EFS = event-free survival; PFR = progression free rate; QOL = quality of life

**Colon Cancer**

| First-line therapy of metastatic colon cancer (mCRC) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Regimen** | **NCCN Category** | **FDA Approved** | **Trial Design** | **Comparator** | **Primary End-Point** | **Line of Therapy** | **Conclusion** |
| Panitumumab + FOLFOX | 2A (for KRAS/ NRAS WT and left-sided tumors only) | Yes | Phase 3 (PRIME), randomized, open-label<br><br>Final results | FOLFOX | PFS | First-line | • Additional RAS mutations predicted a lack of response in patients who received panitumumab-FOLFOX4. In patients who had metastatic colorectal cancer without RAS mutations, improvements in overall survival were observed with panitumumab-FOLFOX4 therapy |
| Panitumumab + FOLFOX | 2A | Yes | Phase 2 (PLANET-TTD), multi-center, open-label | Panitumumab + FOLFIRI | ORR | First-line | • In patients with WT-KRAS mCRC and liver metastases, both first-line P-FOLFOX and P-FOLFIRI resulted in high ORR and early tumor shrinkage, allowing potentially curative resection. No significant differences in efficacy were observed between the two regimens. |
| Bevacizumab (bev) + | 2A | Yes | Phase 3 (Study | IFL + placebo | OS | First-line | • The addition of bevacizumab to fluorouracil-based combination |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| irinotecan + bolus 5FU+ leucovorin (IFL) | | | AVF2107), randomized, double-blind, active-controlled | | | | chemotherapy results in statistically significant improvement in survival (4.7 month increase in median OS) among patients with metastatic colorectal cancer |
| Cetuximab + FOLFIRI | 2A (for KRAS/ NRAS WT and left-sided tumors only) | Yes | Phase 3 (CRYSTAL), randomized, open-label, multi-center<br><br>Updated analysis | FOLFIRI | PFS | First-line | • First-line treatment with cetuximab plus FOLFIRI, as compared with FOLFIRI alone, reduced the risk of progression of metastatic colorectal cancer. The benefit of cetuximab was limited to patients with KRAS wild-type tumors. |
| Cetuximab + FOLFOX | 2A (for KRAS/ NRAS WT and left-sided tumors only) | No | Phase 3 (TAILOR), open-label, randomized | FOLFOX | PFS | First-line | • Combination of FOLFOX with cetuximab is effective in first-line treatment of patients with RAS wild-type mCRC with a benefit in both PFS and OS. |
| Panitumumab + FOLFOX | 2A (for KRAS/ NRAS WT and left-sided tumors only) | Yes | Phase 2 (PEAK), randomized, multi-center | Bevacizumab + FOLFOX | PFS | First-line | • PFS was similar and OS was improved with panitumumab relative to bevacizumab when combined with FOLFOX in patients with wild-type KRAS tumors. |
| Bevacizumab + FOLFIRI | 2A | Yes | Phase 3 (FIRE-3), randomized, open-label<br><br>Primary tumor | Cetuximab + FOLFIRI | ORR | First-line | • The proportion of patients who achieved an objective response did not significantly differ between the FOLFIRI plus cetuximab and FOLFIRI plus bevacizumab. A longer association in OS with FOLFIRI plus cetuximab was demonstrated for patients with KRAS exon 2 wild-type metastatic colorectal cancer. |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | location analysis | | | | • More benefit was shown for cetuximab in left-sided tumors than bevacizumab. |
| Cetuximab + FOLFOX or FOLFIRI | 2A (for KRAS/ NRAS WT and left-sided tumors only) | Yes (with FOLFIRI) | Phase 3 (CALGB/ SWOG 80405), randomized, open-label, multi-center | Bevacizumab (BV) + FOLFOX or FOLFIRI vs. Cetuximab + bevacizumab + FOLFOX or FOLFIRI | OS | First-line for advanced or metastatic disease | • OS and PFS were prolonged with cetuximab in left-sided tumors and with bevacizumab in right-sided tumors. OS and PFS were poorer with cetuximab in right-sided tumors. |
| Bevacizumab-containing regimen | 2A | Yes | Retrospective meta-analysis of FIRE-3, CALGB/ SWOG 80405, & PEAK | Erbitux or Vectibix-containing regimens | --------- | First-line | • RAS wild-type left-sided CRC had a significantly greater survival benefit from anti-EGFR treatment compared with anti-VEGF treatment when added to standard chemo<br>• Bevacizumab was associated with a longer survival in patients with right-sided CRC |
| Panitumumab + bevacizumab + chemotherapy (oxaliplatin- or irinotecan-based) | None | No | Phase 3b (PACCE), randomized | Bevacizumab + chemotherapy (oxaliplatin- or irinotecan-based) | PFS | First-line | • The addition of panitumumab to bevacizumab and oxaliplatin- or irinotecan-based chemotherapy results in increased toxicity and decreased PFS. |
| Cetuximab + bevacizumab + XELOX | None | No | Phase 3 (CAIRO2), randomized | Bevacizumab+ XELOX | PFS | First-line | • PFS was significantly worse with dual antibody therapy. Even patients with wild-type KRAS tumors did not benefit from the addition of cetuximab. |
| **Subsequent therapy of metastatic colon cancer** | | | | | | | |

| Regimen | NCCN Category | FDA Approved | Trial Design | Comparator | Primary End-Point | Line of Therapy | Conclusion |
|---|---|---|---|---|---|---|---|
| Panitumumab | 2A (for KRAS/ NRAS WT) | Yes | Phase 3, open-label, randomized<br><br>Retrospective analysis | Best supportive care (BSC) | PFS | After 2-3 prior line of therapy including oxaliplatin/ irinotecan-based chemotherapy | • Panitumumab monotherapy efficacy in mCRC is confined to patients with WT KRAS tumors |
| Panitumumab + FOLFIRI | 2A | No | Phase 3 (Study 181), randomized | FOLFIRI | PFS<br>OS | Second-line | • Panitumumab plus FOLFIRI significantly improved PFS, however the improvement in OS was nonsignificant |
| Panitumumab | 2A (for KRAS/ NRAS WT) | No | Phase 3 (ASPECCT), randomized, multi-center, open-label, non-inferiority | Cetuximab | Non-inferiority OS | Chemo-refractory | • Panitumumab is non-inferior to cetuximab. These agents provide similar overall survival benefit in patients with KRAS wild type mCRC. |
| Cetuximab + ramucirumab + irinotecan (ICR) | None | No | Phase 2 (E7208), randomized | Cetuximab + irinotecan (IC) | PFS (P<0.15) | Second-line | • In KRAS wild-type CRC second-line therapy, an anti-VEGF antibody combined with anti-EGFR and irinotecan prolongs PFS. |
| Bevacizumab + FOLFIRI | 2A (preferred after previous oxaliplatin- or fluoropyrimidine-based therapy without irinotecan or oxaliplatin) | Yes | Phase 2 (SPIRITT), randomized, multi-center | Panitumumab + FOLFIRI | PFS | Second-line after oxaliplatin-based therapy plus bevacizumab | • Panitumumab or bevacizumab with FOLFIRI as second-line treatment had efficacy similar in patients whose disease progressed during oxaliplatin-based chemotherapy with bevacizumab |

| Subsequent therapy of metastatic colon cancer | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Regimen** | **NCCN Category** | **FDA Approved** | **Trial Design** | **Comparator** | **Primary End-Point** | **Line of Therapy** | **Conclusion** |
| Panitumumab + trametinib + dabrafenib | 2A | No | Phase 1 | N/A | ----- | Subsequent therapy | • Combined BRAF, EGFR. and MEK inhibition demonstrated an ORR of 21% in patients with BRAF V600E mutation positive colorectal cancer that progressed on a prior line of therapy. |