

# Vectibix<sup>®</sup> (panitumumab) (Intravenous)

-E-Document Number: MODA-0389

Last Review Date: 04/04/2024 Date of Origin: 04/03/2019 Dates Reviewed: 04/2019, 07/2019, 09/2019, 01/2020, 04/2020, 07/2020, 10/2020, 01/2021, 04/2021, 07/2021, 10/2021, 02/2022, 05/2022, 10/2022, 01/2023, 05/2023, 07/2023, 10/2023, 01/2024, 04/2024

## 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: 2 vials every 14 days

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

• 70 billable 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

## Colorectal Cancer † ± 1,2,6-8,10,11-12,3e,5e,8e,11e,13e-15e

- Patient has not been previously treated with cetuximab or panitumumab; AND
- Will not be used as part of an adjuvant treatment regimen; AND
- Will not be used in combination with an anti-VEGF agent (e.g., bevacizumab, ramucirumab); **AND** 
  - Patient has both KRAS and NRAS mutation negative (wild-type) and BRAF V600E negative (wild-type) disease as determined by an FDA or CLIA-compliant test\*; AND
    - Used as primary treatment for metastatic or unresectable (or medically inoperable) disease §; AND
      - Used in combination with FOLFOX †; OR
      - Used in combination with CapeOX or FOLFIRI; AND

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- Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR
- Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND
  - Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR
- Used in combination with irinotecan; AND
  - Patient previously received FOLFOX or CapeOX within the past 12 months; AND
  - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR
- Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any <u>rectal</u> cancer; AND
  - $\:$  Used in combination with CapeOX, FOLFOX, or FOLFIRI;  $\ensuremath{\textbf{AND}}$ 
    - Used if resection is contraindicated following total neoadjuvant therapy;
      AND
      - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR
      - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND
        - Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR
    - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; AND
      - ✤ Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR
- Used as subsequent therapy for advanced or metastatic disease; AND
  - Used as a single agent; AND
    - Patient has fluoropyrimidine-, oxaliplatin-, and irinotecan-refractory disease †; OR
    - > Patient has irinotecan-intolerant disease §; AND
      - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR
      - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND

- Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR
- Used in combination with irinotecan §; AND
  - Patient has oxaliplatin-refractory disease, irinotecan-refractory disease, or oxaliplatin- and irinotecan-refractory disease; AND
    - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR
    - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND
      - Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy; OR
- Used in combination with FOLFIRI §; AND
  - > Patient has oxaliplatin-refractory disease\*\*; AND
    - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR
    - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; AND
      - Patient is not a candidate for or has progressed on checkpoint inhibitor immunotherapy

 $\label{eq:color} \ensuremath{\mathcal{S}} \textit{Colon cancer patients must have left-sided tumors only.}$ 

**\*\***May also be used for progression on non-intensive therapy in patients with improvement in functional status (except if received previous fluoropyrimidine).

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 – <u>http://www.fda.gov/companiondiagnostics</u>

FDA Approved 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:

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Page 3/8

- Patient continues to meet the 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>1,6,11-12</sup>

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 (STANDARD)

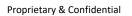
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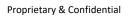
Moda Health Plan, Inc. Medical Necessity Criteria



Page 5/8

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Moda Health Plan, Inc. Medical Necessity Criteria



Page 6/8

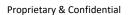
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ICD-10	ICD-10 Description	
C18.0	Malignant neoplasm of cecum	
C18.2	Malignant neoplasm of ascending colon	
C18.3	Malignant neoplasm of hepatic flexure	
C18.4	Malignant neoplasm of transverse colon	
C18.5	Malignant neoplasm of splenic flexure	
C18.6	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	

## Appendix 1 – Covered Diagnosis Codes

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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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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		
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA		
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in	Novitas Solutions, Inc.		
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)		
15	КҮ, ОН	CGS Administrators, LLC		

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

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