



POLICY NUMBER UM_1135	SUBJECT Vectibix™ (panitumumab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 07/22/11, 03/13/13, 07/24/14, 12/16/15, 12/29/16, 12/14/17, 11/09/18, 10/09/19	APPROVAL DATE October 9, 2019	EFFECTIVE DATE October 9, 2019	COMMITTEE APPROVAL DATES (latest version listed last) 07/22/11, 03/13/13, 07/24/14, 12/16/15, 12/29/16, 12/14/17, 11/09/18, 10/09/19	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Oncology	

I. PURPOSE

To define and describe the accepted indications for Vectibix (panitumumab) usage in the treatment of cancer.

II. DEFINITIONS

Vectibix (panitumumab): is a recombinant monoclonal antibody that binds with high affinity to the human epidermal growth factor receptor (EGFR), thus competitively inhibiting ligand-induced receptor autophosphorylation. Binding results in internalization of the receptor, cell growth inhibition, induction of apoptosis, and decreased pro-inflammatory and vascular growth factor production. Mutation of the KRAS gene, a part of the EGFR signaling cascade, may affect response to panitumumab, in that mutated KRAS in the tumor cell may render EGFR inhibitors ineffective.

Vectibix (panitumumab) is FDA approved as a single agent for the treatment of epidermal growth factor receptor (EGFR)-expressing, metastatic colorectal carcinoma (mCRC) with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

Vectibix (panitumumab) is available as 100 mg and 400 mg vials.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Vectibix (panitumumab) may be considered medically necessary when any of the following selection criteria is met:

1. Colorectal Cancer

- a. The member has stage IV metastatic colorectal cancer and Vectibix (panitumumab) is being used for tumors expressing *KRAS/NRAS/BRAF* wild-type gene as **ONE** of the following:
 - i. Initial therapy (left-sided tumors for colon cancer only)
 - A. In combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen for those who can tolerate intensive therapy
 - ii. Recurrent therapy (not previously treated with cetuximab or panitumumab)



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- A. Panitumumab can be used with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan) for disease previously treated with oxaliplatin based chemotherapy WITHOUT irinotecan (i.e. FOLFOX OR CAPEOX) **OR**
 - B. Panitumumab can be used with irinotecan for disease previously treated with irinotecan based chemotherapy WITHOUT oxaliplatin (i.e. FOLFIRI) **OR**
 - C. Panitumumab can be used with irinotecan for disease previously treated with FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) **OR**
 - D. Panitumumab can be used with irinotecan as third line or subsequent line of therapy for disease previously treated with irinotecan and oxaliplatin based regimens.
- b. Vectibix (panitumumab) is being used in combination with irinotecan and vemurafenib for members with unresectable, advanced, or metastatic disease that is BRAF V600E mutation positive.

Exclusion Criteria: Vectibix (panitumumab) is not considered medically necessary when any of the following selection criteria is met:

1. Vectibix (panitumumab) is being used for any of the following:
 - a. In member who has disease progression on Vectibix (panitumumab) or who has failed Erbitux (cetuximab)
 - b. In combination with FOLFOX as second line therapy
2. Dosing exceeds single dose limit of Vectibix (panitumumab) 6mg/kg.
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Vectibix (panitumumab) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration**
 - a. Colorectal Cancer: 6 mg/kg IV infused over 60 min every 14 days; infuse doses higher than 1,000 mg over 90 min
2. **Dosage Adjustments**
 - a. Infusion reactions: mild or moderate (grade 1 or 2), reduce infusion rate by 50%
 - b. Infusion reactions: severe, immediately discontinue; permanently discontinue depending on severity and/or persistence
 - c. Dermatologic toxicities: grade 3 or higher or those considered intolerable, withhold therapy; permanently discontinue if the toxicity does not improve to grade 2 or less within 1 month
 - d. Dermatologic toxicities: if toxicity improves to grade 2 or less with symptomatic improvement after withholding no more than 2 doses, resume treatment at 50% of the original dose; if toxicity recurs, permanently discontinue; if toxicity does not recur, increase dose by increments of 25% of the original dose until 6mg/kg
3. **Monitoring**



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- a. Laboratory Parameters
 - i. Members with metastatic colorectal carcinoma who are candidates for anti-EGFR antibody treatment should have the tumor tested for KRAS mutations in a Clinical Laboratory Improvement Amendments (CLIA)-accredited laboratory. If KRAS mutation in codon 12 or 13 is identified, then the member should not receive anti-EGFR antibody therapy.
 - ii. Monitor electrolytes periodically, especially for hypomagnesemia and hypocalcemia, during treatment and for 8 weeks following the completion of therapy.
- b. Physical Findings
 - i. Monitor for evidence of ocular toxicity, including keratitis and ulcerative keratitis, during therapy

V. APPROVAL AUTHORITY

- 1. Review – UM Department
- 2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

- 1. Vectibix (panitumumab) prescribing information. Amgen Inc. Thousand Oaks, CA. 2017.
- 2. Clinical Pharmacology Elsevier Gold Standard. 2019.
- 3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
- 4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2019.