

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Vectibix (panitumumab)

CG-DRUG-66

Override	Approval Duration
Prior Authorization	6 months

Medication
Vectibix (panitumumab)

APPROVAL CRITERIA:

- I. Vectibix (panitumumab) may be approved when the following criteria are met:
 - A. Individual is using as a single agent or as part of combination therapy for Stage IV colon, rectal, colorectal, small bowel, or anal adenocarcinoma; **AND**
 - B. Extended RAS gene mutation testing with an FDA approved test is documented and the tumor is determined to be RAS wild-type*; **AND**
 - C. Panitumumab (Vectibix) is to be used for only one line of therapy; **AND**
 - D. Vectibix is not being used in combination with anti-VEGF agents (for example bevacizumab); **AND**
 - E. Individual has not received prior treatment** with cetuximab (Erbix)

Notes:

*RAS wild-type means that a genetic mutation in the KRAS, NRAS and BRAF genes is lacking, that is these genes are normal or lacking mutations.

*Note: enough for provider to mark Yes or No on the review form

**A course of cetuximab discontinued because of adverse reaction, not progressive disease, is not considered prior treatment.

Requests for Vectibix (panitumumab) may **not** be approved for:

- I. The treatment of RAS-mutant metastatic colorectal cancer, small bowel or anal adenocarcinoma, (that is, when an FDA approved test has confirmed the presence of

PAGE 1 of 3 04/26/2018

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0071-18

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

- genetic mutations in any of the RAS genes) **or** when RAS mutation status is unknown; **OR**
- II. Penile cancer and squamous cell anal carcinoma; **OR**
 - III. Combination use with other monoclonal antibodies or anti-VEGF agents.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Allegra CJ, Jessup JM, Somerfield MR, et al. American Society of Clinical Oncology provisional clinical opinion: testing for KRAS gene mutations in patients with metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy. J Clin Oncol. 2009; 27(12):2091-2096.
2. Allegra CJ, Rumble RB, Hamilton SR, et al. Extended RAS gene mutation testing in metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. J Clin Oncol. 2016; 34(2):179-185.
3. American Hospital Formulary Service® (AHFS). AHFS Drug Information 2017®. Bethesda, MD: American Society of Health-System Pharmacists®, 2017.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). KRAS mutations and epidermal growth factor receptor inhibitor therapy in metastatic colorectal cancer. TEC Assessments. 2008; 23(6).
5. Evaluation of Genomic Applications in practice and Prevention (EGAPP) Working Group. Recommendations from the EGAPP Working Group: can testing of tumor tissue for mutations in EGFR pathway downstream effector genes in patients with metastatic colorectal cancer improve health outcomes by guiding decisions regarding anti-EGFR therapy? Genet Med. 2013; 15(7):517-527.
6. Medical Advisory Secretariat. KRAS testing for anti-EGFR therapy in advanced colorectal cancer. An evidence-based and economic analysis. Ont Health Technol Assess Ser [Internet]. December 2010. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3377508/pdf/ohtas-10-49.pdf>. Accessed on September 21, 2017.
7. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version). For additional information: <http://www.nccn.org>. Accessed on September 21, 2017.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2017 National Comprehensive Cancer Network, Inc. For additional information: <http://www.nccn.org/index.asp>. Accessed on September 21, 2017.
 - Anal Carcinoma (V.2.2017). Revised April 20, 2017.
 - Colon Cancer (V.2.2017). Revised March 13, 2017.
 - Penile Cancer (V.2.2017). Revised March 10, 2017.
 - Rectal Cancer (V.3.2017). Revised March 13, 2017.
9. Panitumumab. In: DrugPoints System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated August 29, 2017. Available at: <http://www.micromedexsolutions.com>. Accessed on September 28, 2017.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

10. U.S. Food and Drug Administration (FDA). Office of In Vitro Diagnostics and Radiological Health. Accessed on September 22, 2017.
 - In Vitro Companion Diagnostic Devices - Guidance for Industry and Food and Drug Administration Staff. August 6, 2014. Available at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM262327.pdf>. Accessed on September 25, 2017.
 - List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). June 29, 2017. Available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm>. Accessed on September 25, 2017.
11. Vectibix (Panitumumab) [Prescribing Information], Thousand Oaks, CA. Amgen. June, 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125147s207lbl.pdf. Accessed on September 21, 2017.
12. Vectibix (Panitumumab) Injectable Drug Approval Package. May 29, 2007. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/125147s0000TOC.cfm. Accessed on September 21, 2017.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.