

Vectibix (panitumumab)

Line(s) of Business:

HMO; PPO; QUEST Integration
Akamai Advantage

Original Effective Date:

04/01/2008

Current Effective Date:

08/01/2017

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

- Metastatic colorectal cancer
 - Vectibix is indicated for the treatment of patients with wild-type *KRAS* (exon 2 in codons 12 or 13) metastatic colorectal cancer (mCRC) as determined by an FDA-approved test for this use:
 - As first-line therapy in combination with FOLFOX*
 - As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

Limitation of Use:

Vectibix is not indicated for the treatment of patients with *KRAS* mutant mCRC or for whom *KRAS* mutation status is unknown.

Compendial Uses

- Colorectal cancer²

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- For initial therapy
 - Current oncology notes, clinical notes (including previous treatment history), and any pertinent pathology reports and/or imaging studies
 - *RAS* mutations testing (*KRAS* and *NRAS*) mutation testing results on either the primary tumor or metastasis
- For continuation therapy
 - Documentation demonstrating lack of disease progression on therapy

C. PRESCRIBER RESTRICTION

- Vectibix must be prescribed by an oncologist.

D. CRITERIA FOR APPROVAL

1. Colorectal cancer

- a. *RAS* mutation testing (*KRAS* and *NRAS*) was performed on either the primary tumor or metastasis and the tumor is negative for *KRAS* and/or *NRAS* mutations (tumor is wild-type).
- b. Member has any of the following:
 - i. Stage IV (metastatic) disease (see c. below)
 - ii. Colon cancer and clinical T4b disease and Vectibix will be used as neoadjuvant therapy prior to colectomy in combination with FOLFOX or FOLFIRI
 - iii. Rectal cancer and stage II or III disease (T3, N0, M0; any T, N1-2, M0; any T4) and/or locally unresectable or medically inoperable disease in combination with FOLFOX or FOLFIRI
- c. For metastatic disease, Vectibix will be used in one of the settings below and all the related criteria are met:
 - i. Authorization of 3 months may be granted for members who are prescribed Vectibix as perioperative/neoadjuvant therapy for initially resectable* liver and/or lung metastases only, and Vectibix will be used in combination with FOLFOX or FOLFIRI.
 - ii. Authorization of 3 months may be granted for members who are prescribed Vectibix as perioperative/adjuvant therapy for resectable* metachronous metastases when used in combination with FOLFOX or FOLFIRI in members previously treated with chemotherapy.
 - iii. Authorization of 3 months may be granted for members who are prescribed Vectibix as therapy for unresectable metachronous metastases when used in combination with irinotecan or FOLFIRI in members who received adjuvant FOLFOX/CapeOX in the past 12 months.
 - iv. Authorization of 3 months may be granted for members who are prescribed Vectibix as initial therapy for other unresectable advanced or metastatic disease when used in combination with FOLFOX** or FOLFIRI.
 - v. Authorization of 3 months may be granted for members who are prescribed Vectibix as therapy after first progression when ALL of the following criteria are met:
 - 1) Member has not previously received Erbitux (cetuximab) or Vectibix.
 - 2) Vectibix will be used as a single agent or in combination with irinotecan if the member has previously received an irinotecan-based regimen OR in combination with irinotecan or FOLFIRI if the member has previously received an oxaliplatin-based regimen.
 - vi. Authorization of 3 months may be granted for members who prescribed Vectibix as therapy after second progression when ALL of the following criteria are met:
 - 1) Member has not previously received Erbitux (cetuximab) or Vectibix.
 - 2) Vectibix will be used as a single agent or in combination with irinotecan.

* Patients in whom complete resection of all evident disease can be achieved with negative surgical margins and maintaining adequate liver reserve.

** Note: oxaliplatin may be discontinued from FOLFOX after 3-4 months or sooner if significant neurotoxicity develops.

Abbreviations: CapeOX = capecitabine and oxaliplatin; FOLFIRI = leucovorin, fluorouracil, and irinotecan; FOLFOX = leucovorin, fluorouracil, and oxaliplatin

E. CONTINUATION OF THERAPY

Authorization of 3 months may be granted to members requesting authorization for continuation of therapy when ALL of the following criteria are met:

- a. Member has not had disease progression.
- b. Previous Vectibix therapy was authorized by HMSA or member meets all initial criteria.

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

H. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

1. Vectibix [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2015.
2. The NCCN Drugs & Biologics Compendium™. © 2016 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 2, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: colon cancer. Version 2.2016. http://www.nccn.org/professionals/physician_gls/PDF/colon.pdf. Accessed May 31, 2016.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: rectal cancer. Version 2.2016. http://www.nccn.org/professionals/physician_gls/PDF/rectal.pdf. Accessed June 1, 2016.

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