

Policy #: 114

Original policy date: 9/1/09  
Revised date: 10/16/09

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### Title

#### Epidermal Growth Factor Receptor (EGFR) Inhibitors

Erbitux<sup>®</sup> (cetuximab)

Vectibix<sup>®</sup> (panitumumab)

This medication is not covered by the pharmacy benefit. It is covered by the medical benefit only.

### Description

**Erbitux<sup>®</sup>**, an epidermal growth factor receptor (EGFR) inhibitor, is indicated for treatment of metastatic colorectal cancer and squamous cell cancer of the head and neck

**Vectibix<sup>®</sup>**, an epidermal growth factor receptor (EGFR) inhibitor, is indicated for the treatment of refractory metastatic colorectal cancer.

Epidermal growth factor (EGF) plays an important role in regulating cell growth, proliferation, and differentiation by binding with high affinity to the EGFR on the cell surface. Mutations in the EGFR can be found in several types of cancer. Epidermal growth factor receptors have been studied in the development of anticancer therapies. Cetuximab and panitumumab are monoclonal antibodies that bind to the EGF receptor, inhibiting the activation of this receptor.

The RAS-RAF-MAP kinase pathway is activated in the EGFR cascade. RAS proteins are G-proteins that cycle between active (RAS-GTP) and inactive (RAS-GDP) forms, in response to stimulation from a cell surface receptor such as EGFR, and act as a binary switch between the cell surface EGFR and downstream signaling pathways. The KRAS gene can harbor oncogenic mutations that result in a constitutively activated protein, independent of EGFR ligand binding, rendering antibodies to the upstream EGFR ineffective. KRAS mutations are found in approximately 30%–50% of colorectal cancer (CRC)

### When services are covered for Commercial products (excluding Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx plans; see below for coverage for these products)

We cover Erbitux<sup>®</sup> (cetuximab) and Vectibix<sup>®</sup> (panitumumab) when all of the following criteria are met<sup>1</sup>:

- A diagnosis of metastatic colorectal cancer (ICD-9 CM = 153.0 -154.1)
- KRAS testing has been performed and the results indicate that the patient is positive for KRAS wild type (*KRAS WT* also known as *wild type KRAS* )

We cover Erbitux<sup>®</sup> (cetuximab) for a diagnosis of squamous cell cancer of the head or neck.

ICD-9 CM diagnoses codes:

- 140.0-149.9: Malignant neoplasm of lip, oral cavity, and pharynx
- 160.0-162.0: Malignant neoplasm of nasal cavities, ear, sinuses, larynx, trachea
- 171.0: Malignant neoplasm of connective and soft tissues, head, face, and neck
- 195.0: Malignant neoplasm of head, face, and neck
- 198.89: Secondary malignant neoplasm; other specified sites
- 230.0: Carcinoma in situ of lip, oral cavity, and pharynx

- 231.0: Carcinoma in situ of larynx
- 234.8: Carcinoma in situ of other and unspecified sites
- V10.01-V10.02: Personal history of malignant neoplasm, tongue, oral cavity, pharynx

**When services are not covered for Commercial Products (excluding Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx products)**

We do not cover Erbitux or Vectibix for requests that do not meet the criteria above.

**When services are covered for Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRx Products**

These medications are covered for Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRx products.

**Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

Blue Cross Blue Shield of Massachusetts  
 Clinical Pharmacy Operations  
 25 Technology Place  
 Hingham, MA 02043  
 Tel: (800) 366-7778  
 Fax: (888) 641-5355

**Managed care guidelines**

- Prior authorization is required for all out patient sites of service

**Indemnity and PPO guidelines**

- Prior authorization **is** required when these medications are processed under the home infusion therapy benefit.
- Prior authorization **is not** required when these drugs are purchased by the physician and administered in the office in accordance with this medical policy.

**Coding information**

*Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

**HCPCS Codes:**

- **Vectibix<sup>®</sup>, J9303: injection panitumumab 10 mg**

When used with the following for malignant neoplasm of the colon:

**ICD-9 CM diagnosis codes**

- 153.0**, hepatic flexure
- 153.1**, transverse colon

- 153.2, descending colon
- 153.3, sigmoid colon, sigmoid (flexure)
- 153.4, cecum, ileocecal valve
- 153.5, appendix
- 153.6, ascending colon, right colon
- 153.7, splenic flexure
- 153.8, other specified sites of large intestine (malignant neoplasm of contiguous or overlapping sites of colon whose point of origin cannot be determined)
- 153.9, colon, unspecified (large intestine NOS (malignant neoplasm of rectum, rectosigmoid junction, and anus)
- 154.0, rectosigmoid junction (colon with rectum, rectosigmoid (colon)
- 154.1, rectum, rectal ampulla

- **Erbitux<sup>®</sup>, J9055, injection cetuximab, 10 mg**

When used with the following for squamous cell cancer of the head or neck:

**ICD-9 CM diagnosis codes**

- 140.0-149.9:** Malignant neoplasm of lip, oral cavity, and pharynx
- 160.0-162.0:** Malignant neoplasm of nasal cavities, ear, sinuses, larynx, trachea
- 171.0:** Malignant neoplasm of connective and soft tissues, head, face, and neck
- 195.0:** Malignant neoplasm of head, face, and neck
- 198.89:** Secondary malignant neoplasm; other specified sites
- 230.0:** Carcinoma in situ of lip, oral cavity, and pharynx
- 231.0:** Carcinoma in situ of larynx
- 234.8:** Carcinoma in situ of other and unspecified sites
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**Policy update history**

New Policy, effective 9/1/09. Policy updated 10/09 to reflect UM requirements. Reviewed 9/2009 MPG-Hematology and Oncology, no changes in coverage were made. Updated 10/09 to clarify the ICD-9-CM diagnosis codes that meet the medical necessity for coverage of Erbitux<sup>®</sup> (cetuximab) for squamous cell cancer of the head or neck.

**Footnotes**

<sup>1</sup>Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 5/12/09.

**References**

1. Erbitux<sup>®</sup> [package insert] Branchburg, NJ: ImClone Systems Incorporated; November 2008.
2. Vectibix<sup>®</sup> [package insert] Thousand Oaks, CA: Amgen, Inc.; February 2009.
3. 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): 2091-96.

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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Home Infusion Therapy Prior Authorization Form

Please complete and fax with the physician's prescription to: (888) 641-5355. If the patient is a BCBSMA employee, please fax the form to: (617)246-4013

FOR TPN THERAPY, USE MEDICAL POLICY #296 REQUEST FORM

Form with fields for Company name, Contact Name, Phone #, Provider #, Fax#, Address, Patient name, Address, Patient ID#, DOB, Diagnosis, Telephone, Prescribing Physician, PCP name, and address.

Place of Service [ ] Home [ ] SNF [ ] MD office [ ] other (specify)

Primary Therapy

Primary drug name: \_\_\_\_\_ Approximate duration: \_\_\_/\_\_\_/\_\_\_ to \_\_\_/\_\_\_/\_\_\_

Dose: \_\_\_\_\_

Frequency: \_\_\_\_\_ Route of Administration: \_\_\_\_\_ pump: Y\_\_\_ N\_\_\_

Other Therapy

Other drug name: \_\_\_\_\_ Approximate duration: \_\_\_/\_\_\_/\_\_\_ to \_\_\_/\_\_\_/\_\_\_

Dose: \_\_\_\_\_

Frequency: \_\_\_\_\_ Route of Administration: \_\_\_\_\_ pump: Y\_\_\_ N\_\_\_

[ ] If this is a "drug only" authorization request, indicate other services the nursing agency is providing:

Nursing provided by: \_\_\_\_\_ Contact: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Request for 7 Day Coverage: Date of occurrence: \_\_\_\_\_ Request dates: \_\_\_\_\_

Occurrence type: [ ] Hospitalization [ ] Death [ ] Change of Therapy

Physician signature: \_\_\_\_\_

Date: \_\_\_\_\_

OR Copy of prescription REQUIRED with this request.



**Outpatient Medical Prior Authorization Form**

Please complete and fax to: (888) 641-5355

Please contact Pharmacy Operations with questions at (800) 366-7778

If the patient is a BCBSMA employee, please fax the form to: (617) 246-4013

<b>Servicing Provider</b>	<b>Name:</b> <b>NPI Number:</b>	<b>Requesting Provider</b>	<b>Name:</b> <b>NPI Number:</b>
<b>Phone#</b>		<b>Phone#</b>	
<b>Fax#</b>		<b>Fax#</b>	
<b>Contact Person:</b>		<b>Contact Person:</b>	
<b>Patient Name:</b>		<b>DOB</b> ___/___/___	<b>Diagnosis:</b>
<b>Patient BCBSMA ID#</b>			

**Drug/Therapy:**

Drug Name: \_\_\_\_\_ Dates of Service: \_\_\_/\_\_\_/\_\_\_ to \_\_\_/\_\_\_/\_\_\_

Dose: \_\_\_\_\_

Frequency: \_\_\_\_\_

**Additional Clinical (including previous treatment failure):**

Physician signature: \_\_\_\_\_ Date: \_\_\_\_\_