

SPECIALTY GUIDELINE MANAGEMENT

ERBITUX (cetuximab)

POLICY

I. INDICATIONS

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

A. FDA-Approved Indications

Erbix is an epidermal growth factor receptor (EGFR) antagonist indicated for treatment of:

1. Head and Neck Cancer
 - a. In combination with radiation therapy (RT) for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck
 - b. In combination with platinum-based therapy with 5-fluorouracil (5FU) for the treatment of patients with recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck
 - c. For treatment of recurrent or metastatic squamous cell carcinoma of the head and neck for whom prior platinum-based therapy has failed
2. Colorectal Cancer
KRAS mutation-negative (wild-type), EGFR-expressing, metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use:
 - a. In combination with FOLFIRI for first-line treatment
 - b. In combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
 - c. As a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan

Limitation of Use:

Erbix is not indicated for treatment of *Ras*-mutant colorectal cancer.

B. Compendial Uses

1. Colorectal cancer
2. Penile cancer
3. Squamous cell skin cancer
4. Non-small cell lung cancer

II. CRITERIA FOR INITIAL APPROVAL

A. **Colorectal Cancer**

Authorization of 12 months may be granted for treatment of colorectal cancer when the following criteria are met:

1. Tumor is negative (wild-type) for RAS (*KRAS* and *NRAS*) mutations.
2. Member has not previously experienced clinical failure on panitumumab.

B. **Head and Neck Cancer**

Authorization of 12 months may be granted for treatment of head and neck cancer.

C. **Penile Cancer**

Authorization of 12 months may be granted for treatment of metastatic penile cancer.

D. Squamous Cell Skin Cancer

Authorization of 12 months may be granted for treatment of recurrent or metastatic squamous cell skin cancer.

E. Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for treatment of metastatic NSCLC in members with a known sensitizing EGFR mutation (e.g., EGFR exon 19 deletion or exon 21 (L858R) substitution mutation) when Erbitux is used following disease progression on EGFR tyrosine kinase inhibitor therapy (e.g., afatinib, erlotinib, gefitinib).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation therapy must meet all initial authorization criteria.

IV. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

1. Erbitux [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; April 2015.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. August 2, 2016.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancer. Version 1.2016. Available at http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed August 5, 2016.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Colon Cancer. Version 2.2016. https://www.nccn.org/professionals/physician_gls/pdf/colon_blocks.pdf. Accessed August 10, 2016.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Rectal Cancer. Version 2.2016. https://www.nccn.org/professionals/physician_gls/pdf/rectal_blocks.pdf. Accessed August 10, 2016.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Penile Cancer. Version 2.2016. http://www.nccn.org/professionals/physician_gls/PDF/penile.pdf. Accessed August 15, 2016.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 4.2016. http://www.nccn.org/professionals/physician_gls/PDF/nscl.pdf. Accessed August 14, 2016.