Reference number(s)
1892-A

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
Erbitux 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

Limitations of Use:
Erbitux is not indicated for treatment of *Ras*-mutant colorectal cancer or when the results of the *Ras* mutation tests are unknown.

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, L861) 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. REFERENCES

1. Erbitux [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; June 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 17, 2018.