



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Erbix (cetuximab) is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of squamous cell carcinoma of the head and neck and metastatic colorectal cancer. Erbitux is also used off-label for the treatment of squamous cell skin cancer, penile cancer, and non-small cell lung cancer. Epidermal growth factor receptor (EGFR) is a protein involved in the growth and spread of cancer cells that is detected in many human cancers, including those of the head, neck, colon, and rectum. Erbitux competitively blocks the EGFR receptor and prevents the activation of kinases, resulting in inhibition of cell growth and induction of cell death (1).

### **Regulatory Status**

FDA-approved indications: Erbitux (cetuximab) is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of (1):

1. Head and Neck Cancer
  - a. Locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy.
  - b. Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-FU.
  - c. Recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy.
2. Metastatic Colorectal Cancer (CRC)
  - a. K-Ras wild-type, EGFR-expressing, as determined by FDA-approved tests
    - i. In combination with FOLFIRI for first-line treatment.
    - ii. In combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy.
    - iii. 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 the treatment of Ras-mutant colorectal cancer or when the results of the Ras mutation tests are unknown.

- b. BRAF V600E Mutation-Positive Metastatic Colorectal Cancer (CRC)



**ERBITUX  
(cetuximab)**

- i. In combination with encorafenib, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.
3. Locally Advanced or Metastatic Colorectal Cancer (CRC)
  - a. Adult patients with KRAS G12C-mutated locally advanced or metastatic CRC, as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, in combination with adagrasib.

Off-Label Uses: (2-5).

1. Head and Neck cancer Stage III or IV
2. Metastases of squamous cell skin cancer
3. Metastases of penile cancer
4. Non-small cell lung cancer (NSCLC)

Erbix carries a boxed warning for serious infusion reactions and cardiopulmonary arrest. Electrolytes including serum magnesium, potassium, and calcium should be closely monitored during and after Erbitux administration (1).

Safety and effectiveness of Erbitux in pediatric patients have not been established (1).

**Summary**

Erbitux (cetuximab) is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of head and neck cancer and colorectal cancer. Erbitux is also used off-label for the treatment of squamous cell skin cancer, penile cancer, and non-small cell lung cancer. Erbitux carries a boxed warning for serious infusion reactions and cardiopulmonary arrest. The safety and effectiveness of Erbitux in pediatric patients have not been established (1-5).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Erbitux while maintaining optimal therapeutic outcomes.



**BlueCross  
BlueShield.**

Federal Employee Program.

**ERBITUX  
(cetuximab)**

**References**

1. Erbitux [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2021.
2. Krazati [package insert]. San Diego, CA: Mirati Therapeutics, Inc.; June 2024.
3. NCCN Drugs & Biologics Compendium<sup>®</sup> Cetuximab 2025. National Comprehensive Cancer Network, Inc. Accessed on January 27, 2025.
4. NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Non-Small Cell Lung Cancer (Version 3.2025). National Comprehensive Cancer Network, Inc. January 2025. Accessed on January 27, 2025.
5. NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Colon Cancer (Version 6.2024). National Comprehensive Cancer Network, Inc. January 2025. Accessed on January 27, 2025.
6. NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> Penile Cancer (Version 5.2025). National Comprehensive Cancer Network, Inc. January 2025. Accessed on January 27, 2025.