

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Erbitux (cetuximab)

CG-DRUG-67

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications
Erbitux (cetuximab)

APPROVAL CRITERIA:

Notes:

*A course of panitumumab discontinued because of adverse reaction, not progressive disease, is not considered prior treatment.

**If cetuximab is recommended as initial therapy, it should not be used in second or subsequent lines of therapy.

- I. Individual has a diagnosis of Stage IV, KRAS-wild type+ colon, rectal, colorectal, small bowel, appendix or anal adenocarcinoma when all of the following criteria are met:
 - A. The individual has not received prior treatment with panitumumab* (Vectibix; **AND**
 - B. Erbitux is not being used in combination with anti-VEGF agents (for example, Bevacizumab); **AND**
 - C. Erbitux may be used for only one line of therapy**; **AND**
 - D. Erbitux is being used as a single agent or as part of combination therapy.

Notes: +KRAS wild-type means the gene is normal or lacking mutations.

- II. Individual has a diagnosis of squamous cell carcinoma of head and neck (SCCHN) when the following criteria are met:
 - A. The individual has not received prior treatment with panitumumab*; **AND**
 - B. Erbitux is not being used in combination with anti-VEGF agents (for example, Bevacizumab); **AND**
 - C. Erbitux may be used for only one line of therapy**; **AND**
 - D. Erbitux is being used in *one* of the following indications:

1. In combination with radiation therapy, for the treatment of locally or regionally advanced disease; **OR**

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2. As a single agent for the treatment of individuals with recurrent or metastatic disease for whom prior platinum-based therapy has failed **OR**
3. In combination with platinum-based therapy with 5-FU (fluorouracil) as first-line treatment for individuals with recurrent locoregional disease or metastatic SCCHN; **OR**
4. As a single agent or in combination therapy with or without radiation for **any** of the following indications:
 - a. Unresectable locoregional recurrence; **OR**
 - b. Second primary in individuals who have received prior radiation therapy; **OR**
 - c. Resectable locoregional recurrence in individuals who have not received prior radiation therapy; **OR**
 - d. Distant metastases.

- III. Individual is being treated for unresectable regional recurrent or distant metastatic squamous cell carcinoma of the skin when all of the following criteria are met;
- A. The individual has not received prior treatment with panitumumab*; **AND**
 - B. Erbitux is not being used in combination with anti-VEGF agents (for example, Bevacizumab); **AND**
 - C. Erbitux may be used for only one line of therapy**

Erbitux (cetuximab) **may not** be approved when the above criteria are not met and including, but not limited to:

- I. Use as adjuvant therapy after resection and retreatment of squamous cell anal carcinoma.
- II. Treatment of non-small cell lung cancer.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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2. Azzoli C, Baker S, Temin S, Aliff T, et al. 2011 Focused update of 2009 American Society of Clinical Oncology Clinical Practice Guideline update on chemotherapy for stage IV non-small-cell lung cancer. J Clin Oncol. 2011; 29(28):3825-3831.
3. Cetuximab. In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated February 2, 2018. Available at: <http://www.micromedexsolutions.com>. Accessed on April 10, 2018.
4. Cetuximab Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised February 27, 2018. Accessed on April 10, 2018.
5. Erbitux (cetuximab) [Product Information]. Branchburg, NJ. ImClone Systems Incorporated. April 2015. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125084s262lbl.pdf. Accessed on April 10, 2018.
6. National Cancer Institute (NCI). Available at: <http://www.cancer.gov/cancertopics>. Accessed on April 10, 2018.
 - Anal cancer treatment (PDQ®). Last modified February 1, 2018.
 - Colon cancer treatment (PDQ). Last modified February 16, 2018.
 - Laryngeal cancer Treatment (PDQ): Last modified February 8, 2018.
 - Oropharyngeal cancer treatment (PDQ). Last modified March 28, 2018.
 - Rectal cancer treatment (PDQ). Last modified February 16, 2018.
 - Skin cancer treatment (PDQ). Last modified February 1, 2018.
7. National Cancer Institute (NCI) - Head and Neck Cancer. Reviewed March 29, 2017. Available at: <http://www.cancer.gov/cancertopics/factsheet/Sites-Types/head-and-neck>. Accessed on April 10, 2018.
8. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium® (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on April 10, 2018.
9. NCCN Clinical Practice Guidelines in Oncology™. © 2018. National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 9, 2018.
 - Anal carcinoma (V.1.2018). Revised February 6, 2018.
 - Colon cancer (V.2.2018). Revised March 14, 2018.
 - Head and neck cancers (V.1.2018). Revised February 15, 2018.
 - Non-small cell lung cancer (V.3.2018). Revised February 21, 2018.
 - Pancreatic Adenocarcinoma (V.1.2017). Revised February 24, 2017.
 - Penile Cancer (V.2.2018). Revised March 26, 2018.
 - Rectal cancer (V.1.2018). Revised March 14, 2018.
 - Squamous Cell Skin Cancer (V.2.2018). Revised October 5, 2017.
10. Socinski MA, Evans T, Gettinger S, et al. Treatment of stage IV non-small cell lung cancer: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2013; 143(5 Suppl):e341S-e3468S.

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