Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Erbitux (cetuximab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Erbitux (cetuximab)

APPROVAL CRITERIA:

Requests for Erbitux (cetuximab) may be approved if the following criteria are met:

I. Individual has a diagnosis of colon, rectal, colorectal, appendix or anal adenocarcinoma and the following criteria are met (Label, NCCN 2A):
   A. Individual has stage IV disease; **AND**
   B. Extended RAS gene mutation testing with an FDA approved test is confirmed and the tumor is determined to be RAS wild-type[+]; **AND**
   C. Cetuximab is used as a single agent or as part of combination therapy; **AND**
   D. Individual has not received prior treatment with panitumumab*; **AND**
   E. Cetuximab is not being used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab); **AND**
   F. Cetuximab is used in a single line of therapy**;

   [+]**Note:** RAS wild-type means that the KRAS and NRAS genes are normal or lacking mutations.

OR

II. Individual has a diagnosis of squamous cell carcinoma of head and neck (SCCHN), and the following criteria are met:
   A. Individual has not received prior treatment with panitumumab*; **AND**
   B. Cetuximab is not being used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab); **AND**
   C. Cetuximab is used in a single line of therapy**; **AND**
   D. Cetuximab is used in one of the following indications:
      1. In combination with radiation therapy, for the treatment of locally or regionally advanced disease; **OR**
      2. As a single agent for the treatment of individuals with recurrent or metastatic disease for whom prior platinum-based therapy has failed **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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 (NCCN 2A):
   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;

OR

III. Individual has a diagnosis of squamous cell skin carcinoma, and the following criteria are met (NCCN 2A):
   A. Individual has unresectable regional lymph nodes, regional recurrence, or distant metastatic disease; **AND**
   B. Individual has not received prior treatment with panitumumab*; **AND**
   C. Cetuximab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab); **AND**
   D. Cetuximab is used in a single line of therapy**

*__Note:__ A course of panitumumab discontinued because of adverse reaction, not progressive disease, is not considered prior treatment.
**__Note:__ If cetuximab is recommended as initial therapy, it should not be used in second or subsequent lines of therapy.

Requests for Erbitux (cetuximab) may **not** be approved for the following:

I. All other indications not included above; **OR**
II. In combination with other monoclonal antibodies; **OR**
III. Use as adjuvant therapy after resection for colon cancer; **OR**
IV. Treatment of squamous cell anal carcinoma; **OR**
V. Treatment of non-small cell lung cancer.

Note:
Erbitux has a black box warning for infusion reactions and cardiopulmonary arrest. Erbitux can cause serious and fatal infusion reactions; immediately interrupt and permanently discontinue

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

for serious infusion reaction. Cardiopulmonary arrest or sudden death occurred in patients with SCCHN receiving Erbitux with radiation therapy or a cetuximab product with platinum-based therapy and fluorouracil. Monitor serum electrolytes, including serum magnesium, potassium, and calcium, during and after Erbitux administration.

Key References:

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    a. Anal Carcinoma. V1.2020. Revised November 19, 2020.
    b. Head and Neck Cancers. V1.2020. Revised February 12, 2020.
    c. Colon Cancer. V2.2020. Revised March 3, 2020.
    d. Penile Cancer. V1. 2020. Revised January 14, 2020.
    e. Squamous Cell Skin Cancer. V1.2020. Revised October 2, 2019.
    f. Small Bowel Adenocarcinoma. V 1.2020. Revised July 30, 2019.
    g. Non-small Cell Lung Cancer. V3.2020. Revised February 11, 2020.
    h. Rectal Cancer. V2.2020. Revised March 3, 2020.