Erbitux® (cetuximab)

Medical Guideline Disclaimer
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I. Length of Authorization
Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Max Units (per dose and over time) [Medical Benefit]:

<table>
<thead>
<tr>
<th>Weekly</th>
<th>Every two weeks</th>
</tr>
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<tbody>
<tr>
<td>– Load: 100 billable units x 1 dose</td>
<td>120 billable units every 14 days</td>
</tr>
<tr>
<td>– Maintenance Dose: 60 billable units every 7 days</td>
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</table>

III. Initial Approval Criteria
Coverage is provided in the following conditions:

- Patient is 18 years or older; AND

Colorectal Cancer (CRC) †

Patient is both KRAS and NRAS mutation negative (wild-type) as determined by FDA-approved tests; AND

Will not be used as part of an adjuvant treatment regimen; AND

Patient has not been previously treated with cetuximab or panitumumab; AND
Patient must have progressive, metastatic, or unresectable advanced disease; AND
  - Used in combination with irinotecan- or oxaliplatin-based regimens‡; OR
  - Used in combination with a vemurafenib-based regimen in patients with BRAF V600E mutations; OR

- Used as a single agent therapy for metastatic disease †; AND
  - Patient has previously failed on an oxaliplatin- and irinotecan-based regimen; OR
  - Patient is unable to tolerate irinotecan

**Squamous Cell Carcinoma of the Head and Neck (SCCHN) †**

Used in one of the following regimens: †
- In combination with radiation therapy for regionally or locally advanced disease; OR
- As a single agent in recurrent or metastatic disease after failure on platinum-based therapy; OR
- In combination with platinum-based therapy for first-line treatment of recurrent, loco-regional, or metastatic disease; AND

Patient has one of the following sub-types of SCCHN: ‡
- Cancer of the Glottic Larynx
- Cancer of the Hypopharynx
  - Cetuximab may also be used as a single agent for sequential chemoradiation ‡
- Cancer of the Lip
- Cancer of the Nasopharynx
- Cancer of the Oropharynx
  - Cetuximab may also be used as a single agent for sequential chemoradiation ‡
- Cancer of the Supraglottic Larynx
- Ethmoid Sinus Tumors
- Maxillary Sinus Tumors
- Very advanced and recurrent/persistent head and neck cancer
  - Cetuximab may also be used as a single agent for sequential chemoradiation ‡

**Occult Primary Head and Neck Cancers ‡**
- Must be used as initial treatment as a single agent with sequential chemoradiation

**Non-melanoma Skin Cancer (Basal Cell Skin Cancer and Squamous Cell Skin Cancer) ‡**

For regional recurrence or distant metastases
Penile Cancer ‡
- Patient must have metastatic disease; AND
- Must be used for subsequent treatment; AND
- Must be used as a single agent

Non-Small Cell Lung Cancer (NSCLC) ‡
- Patient must have metastatic disease; AND
- Must be used in combination with afatinib; AND
- Must be used as subsequent therapy for sensitizing EGFR mutation-positive tumors; AND
- Patient has progressed on EGFR tyrosine kinase inhibitor therapy (e.g. erlotinib, afatinib, or gefitinib, etc.); AND
  - Patient has asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; OR
  - Patient is T790M negative and has multiple symptomatic systemic lesions

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:
- Patient continues to meet criteria identified above; AND
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion reactions, cardiopulmonary arrest, pulmonary toxicity/interstitial lung disease, dermatologic toxicity, electrolyte abnormalities, etc.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tr>
<td>Colorectal Cancer</td>
<td>400 mg/m² loading dose, then 250 mg/m² every 7 days; OR 500 mg/m² every 14 days</td>
</tr>
<tr>
<td>All other indications</td>
<td>400 mg/m² loading dose, then 250 mg/m² every 7 days</td>
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Limitations/Exclusions
Erbitux® (cetuximab) is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.
Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>J9055</td>
<td>Injection, cetuximab, 10 mg</td>
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Applicable NDCs

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<td>66733-0948-xx</td>
<td>Erbitux 100 mg/50 mL single-use vial; solution for injection</td>
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<tr>
<td>66733-0958-xx</td>
<td>Erbitux 200 mg/100 mL single-use vial; solution for injection</td>
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Applicable Diagnosis Codes

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C00.0</td>
<td>Malignant neoplasm of external upper lip</td>
</tr>
<tr>
<td>C00.1</td>
<td>Malignant neoplasm of external lower lip</td>
</tr>
<tr>
<td>C00.2</td>
<td>Malignant neoplasm of external lip, unspecified</td>
</tr>
<tr>
<td>C00.3</td>
<td>Malignant neoplasm of upper lip, inner aspect</td>
</tr>
<tr>
<td>C00.4</td>
<td>Malignant neoplasm of lower lip, inner aspect</td>
</tr>
<tr>
<td>C00.5</td>
<td>Malignant neoplasm of lip, unspecified, inner aspect</td>
</tr>
<tr>
<td>C00.6</td>
<td>Malignant neoplasm of commissure of lip, unspecified</td>
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<tr>
<td>C00.8</td>
<td>Malignant neoplasm of overlapping sites of lip</td>
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<tr>
<td>C00.9</td>
<td>Malignant neoplasm of lip, unspecified</td>
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<tr>
<td>C01</td>
<td>Malignant neoplasm of base of tongue</td>
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<tr>
<td>C02.0</td>
<td>Malignant neoplasm of dorsal surface of tongue</td>
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<tr>
<td>C02.1</td>
<td>Malignant neoplasm of border of tongue</td>
</tr>
<tr>
<td>C02.2</td>
<td>Malignant neoplasm of ventral surface of tongue</td>
</tr>
<tr>
<td>C02.3</td>
<td>Malignant neoplasm of anterior two-thirds of tongue, part unspecified</td>
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<tr>
<td>C02.4</td>
<td>Malignant neoplasm of lingual tonsil</td>
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<tr>
<td>C02.9</td>
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<td>Malignant neoplasm of upper gum</td>
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<td>Malignant neoplasm of lower gum</td>
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<td>Malignant neoplasm of soft palate</td>
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<tr>
<td>C06.0</td>
<td>Malignant neoplasm of cheek mucosa</td>
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<td>C06.80</td>
<td>Malignant neoplasm of overlapping sites of unspecified parts of mouth</td>
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<td>C06.89</td>
<td>Malignant neoplasm of overlapping sites of other parts of mouth</td>
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<td>Malignant neoplasm of mouth, unspecified</td>
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<td>Malignant neoplasm of tonsillar fossa</td>
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<td>Malignant neoplasm of posterior wall of oropharynx</td>
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<td>Malignant neoplasm of postcricoid region</td>
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<td>Malignant neoplasm of posterior wall of hypopharynx</td>
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<td>C14.0</td>
<td>Malignant neoplasm of pharynx, unspecified</td>
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<td>Malignant neoplasm of Waldeyer's ring</td>
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<td>Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx</td>
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<td>C17.0</td>
<td>Malignant neoplasm duodenum</td>
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<td>Malignant neoplasm jejunum</td>
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<td>Malignant neoplasm ileum</td>
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<td>C17.8</td>
<td>Malignant neoplasm of overlapping sites of small intestines</td>
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<td>Code</td>
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<td>C17.9</td>
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<td>Malignant neoplasm of ascending colon</td>
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<td>C18.3</td>
<td>Malignant neoplasm of hepatic flexure</td>
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<td>Malignant neoplasm of transverse colon</td>
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<td>Malignant neoplasm of splenic flexure</td>
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<td>C18.7</td>
<td>Malignant neoplasm of sigmoid colon</td>
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<td>C18.8</td>
<td>Malignant neoplasm of overlapping sites of large intestines</td>
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<tr>
<td>C18.9</td>
<td>Malignant neoplasm of colon, unspecified</td>
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<tr>
<td>C19</td>
<td>Malignant neoplasm of rectosigmoid junction</td>
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<td>C20</td>
<td>Malignant neoplasm of rectum</td>
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<td>C21.8</td>
<td>Malignant neoplasm of overlapping sites of rectum, anus and anal canal</td>
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<td>Malignant neoplasm of nasal cavity</td>
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<td>Malignant neoplasm of maxillary sinus</td>
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<td>Malignant neoplasm of ethmoidal sinus</td>
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<td>C32.0</td>
<td>Malignant neoplasm of glottis</td>
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<td>Malignant neoplasm of supraglottis</td>
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<td>Malignant neoplasm of subglottis</td>
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<td>Malignant neoplasm of laryngeal cartilage</td>
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<td>Malignant neoplasm of overlapping sites of larynx</td>
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<td>C32.9</td>
<td>Malignant neoplasm of larynx, unspecified</td>
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<tr>
<td>C33</td>
<td>Malignant neoplasm of trachea</td>
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<tr>
<td>C34.00</td>
<td>Malignant neoplasm of unspecified main bronchus</td>
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<td>Malignant neoplasm of right main bronchus</td>
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<td>C34.02</td>
<td>Malignant neoplasm of left main bronchus</td>
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<td>C34.10</td>
<td>Malignant neoplasm of upper lobe, unspecified bronchus or lung</td>
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<tr>
<td>C34.11</td>
<td>Malignant neoplasm of upper lobe, right bronchus or lung</td>
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<td>C34.12</td>
<td>Malignant neoplasm of upper lobe, left bronchus or lung</td>
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<tr>
<td>C34.2</td>
<td>Malignant neoplasm of middle lobe, bronchus or lung</td>
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<tr>
<td>C34.30</td>
<td>Malignant neoplasm of lower lobe, unspecified bronchus or lung</td>
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<tr>
<td>C34.31</td>
<td>Malignant neoplasm of lower lobe, right bronchus or lung</td>
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<td>C34.32</td>
<td>Malignant neoplasm of lower lobe, left bronchus or lung</td>
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<td>C34.80</td>
<td>Malignant neoplasm of overlapping sites of unspecified bronchus and lung</td>
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<td>Code</td>
<td>Description</td>
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<tr>
<td>C34.81</td>
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<td>C34.92</td>
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<td>Unspecified malignant neoplasm of skin of lip</td>
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<tr>
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<td>Squamous cell carcinoma of skin of lip</td>
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<tr>
<td>C44.09</td>
<td>Other specified malignant neoplasm of skin of lip</td>
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<td>C44.121</td>
<td>Squamous cell carcinoma of skin of unspecified eyelid, including canthus</td>
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<tr>
<td>C44.122</td>
<td>Squamous cell carcinoma of skin of right eyelid, including canthus</td>
</tr>
<tr>
<td>C44.129</td>
<td>Squamous cell carcinoma of skin of left eyelid, including canthus</td>
</tr>
<tr>
<td>C44.221</td>
<td>Squamous cell carcinoma of skin of unspecified ear and external auricular canal</td>
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<tr>
<td>C44.222</td>
<td>Squamous cell carcinoma of skin of right ear and external auricular canal</td>
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<td>C44.229</td>
<td>Squamous cell carcinoma of skin of left ear and external auricular canal</td>
</tr>
<tr>
<td>C44.320</td>
<td>Squamous cell carcinoma of skin of unspecified parts of face</td>
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<td>C44.321</td>
<td>Squamous cell carcinoma of skin of nose</td>
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<tr>
<td>C44.329</td>
<td>Squamous cell carcinoma of skin of other parts of face</td>
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<tr>
<td>C44.42</td>
<td>Squamous cell carcinoma of skin of scalp and neck</td>
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<td>C44.520</td>
<td>Squamous cell carcinoma of anal skin</td>
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<td>C44.521</td>
<td>Squamous cell carcinoma of skin of breast</td>
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<td>C44.529</td>
<td>Squamous cell carcinoma of skin of other part of trunk</td>
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<td>C44.629</td>
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<td>C44.721</td>
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<td>C44.92</td>
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<tr>
<td>C60.0</td>
<td>Malignant neoplasm of prepuce</td>
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<td>Malignant neoplasm of penis, unspecified</td>
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<tr>
<td>C63.7</td>
<td>Malignant neoplasm of other specified male genital organs</td>
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<td>Description</td>
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<tr>
<td>C63.8</td>
<td>Malignant neoplasm of overlapping sites of male genital organs</td>
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<td>C76.0</td>
<td>Malignant neoplasm of head, face and neck</td>
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<td>Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck</td>
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<td>C78.6</td>
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<td>C78.7</td>
<td>Secondary malignant neoplasm of liver and intrahepatic bile duct</td>
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<td>Secondary malignant neoplasm of other digestive organs</td>
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<tr>
<td>D37.01</td>
<td>Neoplasm of uncertain behavior of lip</td>
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Revision History

N/A

VI. References

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cetuximab. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE
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