

Erbitux® (cetuximab) (Intravenous)

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I. Length of Authorization ¹

Coverage will be provided for six months and may be renewed unless otherwise specified.

- SCCHN in combination with radiation therapy: Coverage will be provided for the duration of radiation therapy (6-7 weeks).

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

	Weekly	Every two weeks
Erbitux 100 mg/50 mL solution for injection	1 vial every 7 days	1 vial every 14 days
Erbitux 200 mg/100 mL solution for injection	3 vials every 7 days (5 vials for first dose only)	6 vials every 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Weekly	Every two weeks
– Load: 100 billable units x 1 dose – Maintenance Dose: 60 billable units every 7 days	120 billable units every 14 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Colorectal Cancer (CRC) † ‡ ^{1,2,12,13}

- Patient is both KRAS and NRAS mutation negative (wild-type) as determined by an FDA-approved or CLIA-compliant test*; **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 has metastatic, unresectable (or medically inoperable), or advanced disease that is BRAF mutation negative (wild-type); **AND**
 - Used as primary treatment; **AND**
 - Used in combination with FOLFIRI †; **OR**
 - Used in combination with FOLFOX (*Note: Colon cancer patients must have left sided tumors*); **OR**
 - Used in combination with irinotecan after previous adjuvant FOLFOX or CapeOX within the past 12 months; **OR**
 - Used as subsequent therapy; **AND**
 - Used in combination with irinotecan for oxaliplatin- and/or irinotecan-refractory disease; **OR**
 - Used in combination with FOLFIRI for oxaliplatin-refractory disease; **OR**
 - Used in combination with FOLFOX for irinotecan-refractory disease; **OR**
 - Used as a single agent for oxaliplatin- and/or irinotecan-refractory disease OR irinotecan-intolerant disease; **OR**
 - Patient has BRAF V600E mutation positive disease; **AND**
 - Used in combination with encorafenib; **AND**
 - Used as subsequent therapy for disease progression after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
 - Used as primary treatment for unresectable metastatic disease after previous adjuvant FOLFOX or CapeOX within the past 12 months

Squamous Cell Carcinoma of the Head and Neck (SCCHN) † ⊕ 1,2,25

- Used in one of the following regimens: †
 - In combination with radiation therapy for first-line treatment of regionally or locally advanced disease; **OR**
 - As a single agent for recurrent or metastatic disease after failure on platinum-based therapy; **OR**
 - In combination with platinum-based therapy for first-line treatment of recurrent locoregional 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 as sequential systemic therapy/radiation after induction chemotherapy for T4a, N0-3 disease ‡
 - Cancer of the Lip (Mucosa)
 - Cancer of the Nasopharynx
 - Cancer of the Oral Cavity
 - Cancer of the Oropharynx
 - Cetuximab may also be used as a single agent as sequential systemic therapy/radiation after induction chemotherapy ‡

- Cancer of the Supraglottic Larynx
- Ethmoid Sinus Tumors
 - Cetuximab may also be used as a single agent as sequential systemic therapy/radiation after a complete response to primary systemic therapy ‡
- Maxillary Sinus Tumors
- Very Advanced Head and Neck Cancer (i.e., newly diagnosed locally advanced T4b (M0) disease, newly diagnosed unresectable nodal disease, metastatic disease at initial presentation (M1), recurrent or persistent disease, or patients unfit for surgery)
 - Cetuximab may also be used as one of the following:
 - First-line therapy or subsequent therapy as a single agent for non-nasopharyngeal cancer
 - Subsequent therapy in combination with platinum-based therapy for non-nasopharyngeal cancer (*except for locoregional recurrence without prior radiation therapy*)
 - Sequential systemic therapy/radiation in patients with non-nasopharyngeal cancer as a single agent following induction therapy or combination systemic therapy for recurrent disease
 - Subsequent therapy in combination with carboplatin for nasopharyngeal cancer

Occult Primary Head and Neck Cancers ‡ 2,25

- Used as initial treatment as a single agent as sequential systemic therapy/radiation following induction chemotherapy

Squamous Cell Skin Cancer ‡ 2,27

- Used as a single agent; **AND**
 - Patient is ineligible for or progressed on immune checkpoint inhibitor therapy and clinical trials; **AND**
 - Patient has locally advanced, high-risk, or very high-risk disease; **AND**
 - Curative surgery and curative radiation therapy are not feasible; **AND**
 - Used as primary systemic therapy for non-surgical candidates; **OR**
 - Used as post-operative systemic therapy if residual disease is present and further surgery is not feasible; **OR**
 - Patient has inoperable or not fully resectable new regional disease and curative radiation therapy is not feasible; **OR**
 - Used for regional recurrence or distant metastases; **OR**
- Used as a single agent in combination with radiation therapy; **AND**
 - Patient has locally advanced, high-risk, or very high-risk disease; **AND**
 - Used as primary systemic therapy for non-surgical candidates; **OR**
 - Used as post-operative systemic therapy if residual disease is present and further surgery is not feasible; **OR**

- Patient has new regional disease; **AND**
 - Patient has high-risk regional disease with pathologic extracapsular extension (ECE) or incompletely excised nodal disease; **OR**
 - Patient has inoperable or not fully resectable disease; **OR**
- Used for regional recurrence or distant metastases

Penile Cancer †^{2,26}

- Used as a single agent; **AND**
- Used as subsequent therapy for metastatic disease

Non-Small Cell Lung Cancer (NSCLC) †^{2,24}

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used in combination with afatinib; **AND**
- Used as subsequent therapy for EGFR mutation-positive (e.g., exon 19 deletion or L858R) tumors; **AND**
- Patient has progressed on EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, afatinib, gefitinib, dacomitinib, osimertinib, etc.); **AND**
 - Patient has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases; **OR**
 - Patient has multiple symptomatic systemic lesions; **AND**
 - Patient is T790M negative; **OR**
 - Patient is T790M positive and has progressed on osimertinib therapy

**If confirmed using an FDA approved assay - <http://www.fda.gov/companiondiagnostics>*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ^{1,2,14-27}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by 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: anaphylactic reactions, severe infusion reactions, cardiopulmonary arrest, pulmonary toxicity/interstitial lung disease, dermatologic toxicity, hypomagnesemia/electrolyte abnormalities, etc.

V. Dosage/Administration ^{1,20-23}

Indication	Dose
Colorectal Cancer	400 mg/m ² loading dose intravenously, then 250 mg/m ² intravenously every 7 days until disease progression or unacceptable toxicity OR 500 mg/m ² intravenously every 14 days until disease progression or unacceptable toxicity
NSCLC	500 mg/m ² intravenously every 14 days until disease progression or unacceptable toxicity
SCCHN	<u>In combination with radiation therapy:</u> 400 mg/m ² loading dose, then 250 mg/m ² every 7 days for the duration of radiation therapy (6-7 weeks) <u>Monotherapy or in combination with platinum-based therapy:</u> 400 mg/m ² loading dose, then 250 mg/m ² every 7 days until disease progression or unacceptable toxicity OR 500 mg/m ² intravenously every 14 days until disease progression or unacceptable toxicity
Occult Primary	400 mg/m ² loading dose, then 250 mg/m ² every 7 days until disease progression or unacceptable toxicity OR 500 mg/m ² intravenously every 14 days until disease progression or unacceptable toxicity
Squamous Cell Skin Cancer & Penile Cancer	400 mg/m ² loading dose, then 250 mg/m ² every 7 days until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J9055 – Injection, cetuximab, 10 mg; 1 billable unit = 10 mg.

NDC(s):

- Erbitux 100 mg/50 mL single-use vial; solution for injection: 66733-0948-xx
- Erbitux 200 mg/100 mL single-use vial; solution for injection: 66733-0958-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip
C00.2	Malignant neoplasm of external lip, unspecified
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth

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ICD-10	ICD-10 Description
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06.0	Malignant neoplasm of cheek mucosa
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C09.9	Malignant neoplasm of tonsil, unspecified
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C10.9	Malignant neoplasm of oropharynx, unspecified
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx

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ICD-10	ICD-10 Description
C17.0	Malignant neoplasm duodenum
C17.1	Malignant neoplasm jejunum
C17.2	Malignant neoplasm ileum
C17.8	Malignant neoplasm of overlapping sites of small intestines
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of large intestines
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C30.0	Malignant neoplasm of nasal cavity
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung

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ICD-10	ICD-10 Description
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C44.00	Unspecified malignant neoplasm of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.09	Other specified malignant neoplasm of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis
C60.2	Malignant neoplasm of body of penis
C60.8	Malignant neoplasm of overlapping sites of penis
C60.9	Malignant neoplasm of penis, unspecified
C63.7	Malignant neoplasm of other specified male genital organs

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ICD-10	ICD-10 Description
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C76.0	Malignant neoplasm of head, face and neck
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
D37.01	Neoplasm of uncertain behavior of lip
D37.02	Neoplasm of uncertain behavior of tongue
D37.05	Neoplasm of uncertain behavior of pharynx
D37.09	Neoplasm of uncertain behavior of other specified sites of the oral cavity
D38.0	Neoplasm of uncertain behavior of larynx
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC