Billing and Coding Guide:

With Dosing, Distribution, and Co-pay Information

ERBITUX®
CETUXIMAB
INJECTION FOR INTRAVENOUS INFUSION
100 MG/50 ML & 200 MG/100 ML VIALS

INDICATIONS

Metastatic Colorectal Cancer (mCRC)

ERBITUX® (cetuximab) is indicated for the treatment of *KRAS* wild-type, epidermal growth factor receptor (EGFR)-expressing, mCRC as determined by an FDA-approved test for this use:

- In combination with FOLFIRI (irinotecan, fluorouracil, leucovorin) for first-line treatment
- In combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
- 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 treatment of *RAS*-mutant colorectal cancer or when the results of the *RAS* mutation tests are unknown

ERBITUX is indicated, in combination with encorafenib, for the treatment of adult patients with mCRC with a *BRAF* V600E mutation, as detected by an FDA-approved test, after prior therapy

Head and Neck Cancer

- ERBITUX, in combination with RT, is indicated for the initial treatment of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN)
- ERBITUX is indicated in combination with CT for the first-line treatment of patients with recurrent locoregional disease or metastatic SCCHN
- ERBITUX, as a single agent, is indicated for the treatment of patients with recurrent or metastatic SCCHN for whom prior platinum-based therapy has failed

WARNING: INFUSION REACTIONS AND CARDIOPULMONARY ARREST

Infusion Reactions - ERBITUX can cause serious and fatal infusion reactions. Severe (Grades 3 and 4) infusion reactions occurred in 2.2% of patients receiving ERBITUX in clinical trials.

- **The risk of anaphylactic reactions may be increased in patients with a history of tick bites, red meat allergy, or in the presence of IgE antibodies directed against galactose-α-1,3-galactose (alpha-gal). Consider testing patients for alpha-gal IgE antibodies using FDA-cleared methods prior to initiating ERBITUX. Negative results for alpha-gal antibodies do not rule out the risk of severe infusion reactions.**
- **Approximately 90% of the severe infusion reactions occurred with the first infusion of ERBITUX despite premedication with antihistamines.**
  - **Serious infusion reactions, requiring immediate medical intervention, included symptoms of rapid onset of airway obstruction (bronchospasm, stridor, hoarseness), hypotension, shock, loss of consciousness, myocardial infarction, and/or cardiac arrest. Immediately interrupt and permanently discontinue ERBITUX infusion for serious infusion reactions.**
  - **Caution must be exercised with every ERBITUX infusion as infusion reactions may occur during or several hours following completion of the infusion.**
  - **Premedicate with a histamine-1 (H1) receptor antagonist as recommended.**
  - **Monitor patients for at least 1 hour following each ERBITUX infusion in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis. In patients requiring treatment for infusion reactions, monitor for more than 1 hour to confirm resolution of the reaction. Interrupt the infusion and upon recovery, resume the infusion at a slower rate or permanently discontinue ERBITUX based on severity.**

Cardiopulmonary Arrest - ERBITUX can cause cardiopulmonary arrest. Cardiopulmonary arrest or sudden death occurred in 2% of 208 patients with squamous cell carcinoma of the head and neck receiving radiation therapy and ERBITUX in BONNER. In 3 patients with prior history of coronary artery disease, death occurred 27, 32, and 43 days respectively after the last dose of ERBITUX. One patient with no prior history of coronary artery disease died one day after the last dose of ERBITUX. In EXTREME, fatal cardiac disorders and/or sudden death occurred in 3% of the 219 patients with squamous cell carcinoma of the head and neck treated with a cetuximab product in combination with platinum-based therapy and fluorouracil.

- **Carefully consider the use of ERBITUX with radiation therapy, or with platinum-based therapy with fluorouracil, in head and neck cancer patients with a history of coronary artery disease, congestive heart failure, or arrhythmias.**
- **Closely monitor serum electrolytes, including serum magnesium, potassium, and calcium, during and after ERBITUX therapy.**

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Individual coding decisions should be based upon diagnosis and treatment of individual patients. Eli Lilly and Company does not guarantee success in obtaining insurance payments. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies. Please consult with your legal counsel or reimbursement specialist for any reimbursement or billing questions. For more information, please call the Lilly Support Services™ for Oncology at 1-800-545-5979.

CT=platinum-based therapy and fluorouracil; FDA=U.S. Food and Drug Administration; KRAS=Kirsten rat sarcoma; RAS=Rat sarcoma; RT=radiation therapy.

Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

Lilly

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Lilly

ERBITUX Dosing and Administration for mCRC

Recommended Dosing for mCRC[1]

Weekly OR **Bi-weekly**

INDICATION:
For *KRAS* wild-type, EGFR-expressing mCRC as determined by an FDA-approved test for this use:

- In combination with FOLFIRI first-line
- In combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
- 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 treatment of *RAS*-mutant colorectal cancer or when the results of the *RAS* mutation tests are unknown

Recommended dosage for ERBITUX as a single agent or ERBITUX in combination with irinotecan or FOLFIRI

Weekly Dosage

- Initial dose: 400 mg/m^2 administered as a 120-minute IV infusion
- Subsequent doses: 250 mg/m^2 administered as a 60-minute infusion every week

Bi-weekly Dosage

- Initial and subsequent doses: 500 mg/m^2 administered as a 120-minute IV infusion every 2 weeks

Premedicate with an H_1 antagonist intravenously 30-60 minutes prior to the first dose or subsequent doses as deemed necessary.

Complete ERBITUX administration 1 hour prior to irinotecan or FOLFIRI. Continue treatment until disease progression or unacceptable toxicity.

Determine EGFR-expression status using FDA-approved tests prior to initiating treatment. Also confirm the absence of a *RAS* mutation prior to initiation of treatment with ERBITUX. Patients whose tumors have a *RAS* mutation or whose *RAS* mutational status is unknown should not receive ERBITUX.

Weekly

INDICATION:
In combination with encorafenib, for the treatment of adult patients with mCRC with a *BRAF* V600E mutation, as detected by an FDA-approved test, after prior therapy

Recommended dosage for ERBITUX in combination with encorafenib[1]

Weekly Dosage Only

Week 1

- Initial dose: ERBITUX 400 mg/m^2 IV on day 1
  — Infuse over 120 minutes

Week 2 and beyond

- Subsequent doses: ERBITUX 250 mg/m^2 IV weekly, starting on day 8
  — Infuse over 60 minutes

Premedicate with an H_1 receptor antagonist intravenously 30-60 minutes prior to the first dose or with ERBITUX subsequent doses as deemed necessary.

Continue treatment with ERBITUX plus encorafenib until disease progression or unacceptable toxicity.

ERBITUX is indicated for use as part of a regimen in combination with encorafenib. Refer to the encorafenib Prescribing Information for recommended encorafenib dosing information.

BEACON CRC (NCT02928224)=Binimetinib, Encorafenib, and Cetuximab Combined to Treat *BRAF*-Mutant Colorectal Cancer

BEACON CRC treatment regimen=ERBITUX + encorafenib

- Confirm the presence of a *BRAF* V600E mutation in tumor specimens prior to initiating encorafenib, using an FDA-approved test

For information on dose modifications (eg, infusion reactions, dermatologic toxicity, pulmonary toxicity), and preparation/administration, please see further details on page 5.

CRC=colorectal cancer; H_1=histamine-1; IV=intravenous.

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SELECT IMPORTANT SAFETY INFORMATION

Pulmonary Toxicity

- ERBITUX can cause interstitial lung disease (ILD). ILD, which was fatal in one case, occurred in <0.5% of 1570 patients receiving ERBITUX in clinical trials. Monitor patients for signs and symptoms of pulmonary toxicity. Interrupt or permanently discontinue ERBITUX for acute onset or worsening of pulmonary symptoms. Permanently discontinue ERBITUX for confirmed ILD.

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ERBITUX Dosing and Administration for SCCHN

Recommended Dosing for SCCHN[1]

Weekly OR Bi-weekly

INDICATION:
- First-line for recurrent locoregional or metastatic SCCHN in combination with CT
- As a single agent for the treatment of patients with recurrent or metastatic SCCHN for whom prior platinum-based therapy has failed

Recommended dosage for ERBITUX as a single agent or ERBITUX in combination with platinum-based therapy and fluorouracil

Weekly Dosage
- Initial dose: 400 mg/m^2 administered as a 120-minute IV infusion
- Subsequent doses: 250 mg/m^2 administered as a 60-minute infusion every week

Bi-weekly Dosage
- Initial and subsequent doses: 500 mg/m^2 administered as a 120-minute IV infusion every two weeks

Premedicate with an H_1 antagonist intravenously 30-60 minutes prior to the first dose or subsequent doses as deemed necessary.

Complete ERBITUX administration 1 hour prior to platinum-based therapy with fluorouracil. Continue treatment until disease progression or unacceptable toxicity.

Weekly

INDICATION:
Initial treatment for locoregionally advanced SCCHN in combination with RT

Recommended dosage for ERBITUX with RT dosing schedule for locoregionally advanced SCCHN[1]

Weekly Dosage ONLY

Week 0
- Premedicate with an H_1 antagonist (eg, 50 mg diphenhydramine) IV 30-60 minutes prior to the first dose
- ERBITUX initial dose of 400 mg/m^2 IV over 2 hours administered 1 week prior to the start of RT

Weeks 1-7
- Premedication should be administered for subsequent doses based upon clinical judgment and presence/severity of prior infusion reactions
- ERBITUX subsequent weekly doses of 250 mg/m^2 IV over 1 hour for the duration of RT (6-7 weeks)

Complete ERBITUX administration 1 hour prior to RT.[1]

Radiation therapy
The radiation regimen to be used with ERBITUX is at the discretion of the treating physician.[2]

For information on dose modifications (eg, infusion reactions, dermatologic toxicity, pulmonary toxicity), and preparation/administration, please see further details on page 5.

SELECT IMPORTANT SAFETY INFORMATION

Dermatologic Toxicities

- ERBITUX can cause dermatologic toxicities, including acneiform rash, skin drying and fissuring, paronychial inflammation, infectious sequelae (e.g., S. aureus sepsis, abscess formation, cellulitis, blepharitis, conjunctivitis, keratitis/ulcerative keratitis with decreased visual acuity, cheilitis), and hypertrichosis
  - Acneiform rash occurred in 82% of the 1373 patients who received ERBITUX across clinical trials. Severe (Grades 3 or 4) acneiform rash occurred in 10% of patients. Acneiform rash usually developed within the first 2 weeks of therapy; the rash lasted more than 28 days after stopping ERBITUX in most patients.

Please see next page for additional information on Dermatologic Toxicities.

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ERBITUX Dose Modifications for Adverse Reactions and Preparation and Administration[1]

Reduce, delay, or discontinue ERBITUX to manage adverse reactions as described below:

Adverse reaction	Severity*	Dosage modification
Infusion reactions	Grades 1 or 2	Reduce the infusion rate by 50%.
	Grades 3 or 4	Immediately and permanently discontinue ERBITUX.
Dermatologic toxicities and infectious sequelae (e.g., acneiform rash, mucocutaneous disease)	1st occurrence; Grades 3 or 4	Delay infusion 1 to 2 weeks; if condition improves, continue at 250 mg/m^2. If no improvement, discontinue ERBITUX.
	2nd occurrence; Grades 3 or 4	Delay infusion 1 to 2 weeks; if condition improves, continue at 200 mg/m^2. If no improvement, discontinue ERBITUX.
	3rd occurrence; Grades 3 or 4	Delay infusion 1 to 2 weeks; if condition improves, continue at 150 mg/m^2. If no improvement, discontinue ERBITUX.
	4th occurrence; Grades 3 or 4	Discontinue ERBITUX.
Pulmonary toxicity	Acute onset or worsening pulmonary symptoms	Delay infusion 1 to 2 weeks; if condition improves, continue at the dose that was being administered at the time of occurrence. If no improvement in 2 weeks or interstitial lung disease (ILD) is confirmed, discontinue ERBITUX.

*National Cancer Institute (NCI) Common Toxicity Criteria (CTC), version 2.0.

Preparation and administration:

- Visually inspect for foreign particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be clear and colorless and may contain a small amount of easily visible, white, amorphous, cetuximab particulates. Do not use if solution is discolored, cloudy, or contains foreign particulate matter
- Do not shake or dilute
- Do not administer ERBITUX as an intravenous push or bolus
- Administer via infusion pump or syringe pump; do not exceed an infusion rate of 10 mg/min
- Administer through a low protein binding 0.22-micrometer in-line filter

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SELECT IMPORTANT SAFETY INFORMATION

Dermatologic Toxicities (Continued)

- Life-threatening and fatal bullous mucocutaneous disease with blisters, erosions, and skin sloughing has been observed in patients who received ERBITUX. It could not be determined whether these mucocutaneous adverse reactions were directly related to EGFR inhibition or to idiosyncratic immune-related effects (e.g., Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Monitor patients receiving ERBITUX for dermatologic toxicities and infectious sequelae.
- Sun exposure may exacerbate these effects. Instruct patients to limit sun exposure during ERBITUX therapy.
- Withhold, reduce dose or permanently discontinue ERBITUX based on severity of acneiform rash or mucocutaneous disease.

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ERBITUX Billing and Coding Information

Diagnosis codes

All coding and documentation requirements for drugs must be confirmed with each payer.

- International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes are used to identify a patient's diagnosis. The codes provided below by Lilly should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Use the following ICD-10-CM diagnosis codes for the labeled indications for ERBITUX
- The ICD-10-CM diagnosis codes contain categories, subcategories, and codes. Characters for categories, subcategories, and codes may be letters or numerals
- All categories are 3 characters
- Subcategories are either 4 or 5 characters
- Codes may be 3, 4, 5, 6, or 7 characters

Diagnosis Codes for Colorectal Cancer[3]

ICD-10 Code	Description
C18	**Malignant neoplasm of colon**
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 colon
C18.9	Malignant neoplasm of colon, unspecified
C19	**Malignant neoplasm of rectosigmoid junction**
C20	**Malignant neoplasm of rectum**
C21	**Malignant neoplasm of anus and anal canal**
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus, and anal canal
C78	**Secondary malignant neoplasm of respiratory and digestive organs**
C78.5	Secondary malignant neoplasm of large intestine and rectum

Diagnosis Codes for Head and Neck Cancer[3]

ICD-10 Code	Description
C00	**Malignant neoplasm of lip**
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**

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Lilly and its agents make no guarantee regarding reimbursement for any service or item.

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ERBITUX Billing and Coding Information

Diagnosis codes (continued)

Diagnosis Codes for Head and Neck Cancer[3] (continued)

ICD-10 Code	Description
C02	**Malignant neoplasm of other and unspecified parts 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	**Malignant neoplasm of gum**
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04	**Malignant neoplasm of floor of mouth**
C04.0	Malignant neoplasm of anterior floor of mouth
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

ICD-10 Code	Description
C05	**Malignant neoplasm of palate**
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.2	Malignant neoplasm of uvula
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06	**Malignant neoplasm of other and unspecified parts of mouth**
C06.0	Malignant neoplasm of cheek mucosa
C06.1	Malignant neoplasm of vestibule of mouth
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	**Malignant neoplasm of tonsil**
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

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ERBITUX Billing and Coding Information

Diagnosis codes (continued)

Diagnosis Codes for Head and Neck Cancer[3] (continued)

ICD-10 Code	Description
C10	**Malignant neoplasm of oropharynx**
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
C12	**Malignant neoplasm of pyriform sinus**
C13	**Malignant neoplasm of hypopharynx**
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	**Malignant neoplasm of other and ill-defined sites in the lip, oral cavity, and pharynx**
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

ICD-10 Code	Description
C30	**Malignant neoplasm of nasal cavity**
C30.0	Malignant neoplasm of nasal cavity
C31	**Malignant neoplasm of accessory sinuses**
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C31.2	Malignant neoplasm of frontal sinus
C31.3	Malignant neoplasm of sphenoid sinus
C31.8	Malignant neoplasm of overlapping sites of accessory sinuses
C31.9	Malignant neoplasm of accessory sinus, unspecified
C32	**Malignant neoplasm of larynx**
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
C76	**Malignant neoplasm of other and ill-defined sites**
C76.0	Malignant neoplasm of head, face, and neck

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ERBITUX Billing and Coding Information

HCPCS codes

ERBITUX Specific Code	Description	Setting
J9055	**Injection, cetuximab, 10 mg**	■ **Physician office:** CMS-1500 (paper format) or ASC 837P (electronic format) ■ **Hospital outpatient:** CMS-1450 (UB-04) (paper format) or ASC 837I (electronic format)

All of the coding information is applicable to outpatient procedures only. Typically, there is no need to further identify ERBITUX when billing with HCPCS code J9055.

Drug Administration CPT® codes[4]*

CPT Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)
96417	Each additional sequential infusion (different substance/drug); up to 1 hour (list separately in addition to code for primary procedure)†

SELECT IMPORTANT SAFETY INFORMATION

Risks Associated with Use in Combination with Radiation and Cisplatin

- ERBITUX is not indicated for the treatment of SCCHN in combination with radiation and cisplatin.
- In a controlled study, 940 patients with locally advanced SCCHN were randomized 1:1 to receive either ERBITUX in combination with radiation therapy and cisplatin, or radiation therapy and cisplatin alone. The addition of ERBITUX resulted in an increase in the incidence of Grade 3 and 4 mucositis, radiation recall syndrome, acneiform rash, cardiac events, and electrolyte disturbances compared to radiation and cisplatin alone.
- Adverse reactions with fatal outcome were reported in 4% of patients in the ERBITUX combination arm and 3% in the control arm.
- In the ERBITUX arm, 2% experienced myocardial ischemia compared to 0.9% in the control arm.
- The addition of ERBITUX to radiation and cisplatin did not improve progression-free survival (the primary endpoint).

*CPT codes and descriptions only are © 2012 by American Medical Association. All rights reserved. The association assumes no liability for data contained or not contained herein. CPT® is a registered trademark of the American Medical Association.
†Typically not applicable for the administration of ERBITUX but may be used if different substances are administered sequentially.
CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

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ERBITUX Billing and Coding Information (continued)

NDC codes

The NDCs for ERBITUX, listed here, are often necessary, in addition to the appropriate J- or C-code when filing a claim for reimbursement.

Vial Size	NDC
100 mg/50 mL	66733-948-23 66733-0948-23
200 mg/100 mL	66733-958-23 66733-0958-23

5010 electronic transaction coding for ERBITUX

- For electronic transactions, including 837P and 837I, the NDC is to be preceded with the qualifier N4 and followed immediately by the 11-digit NDC code for payers who require it[5]
- This is typically followed by the NDC unit of measure: UN (units), F2 (international units), GR (gram), or mL (milliliter) of the amount administered[5]

How Supplied	NDC	NDC Qualifier	NDC Basis of Measurement	Sample NDC 5010 Format
100 mg/50 mL, single-use vial	66733-0948-23	N4	mL	N466733094823ML50
200 mg/100 mL, single-use vial	66733-0958-23	N4	mL	N466733095823ML100

The example given in the far right column demonstrates NDC quantity reporting for 1 vial of ERBITUX. The actual amount of drug used can vary based on factors such as patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Lilly and its agents make no guarantee regarding reimbursement for any service or item.

NDC=National Drug Code.

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SELECT IMPORTANT SAFETY INFORMATION

Hypomagnesemia and Accompanying Electrolyte Abnormalities

- ERBITUX can cause hypomagnesemia. Hypomagnesemia occurred in 55% of 365 patients receiving ERBITUX in study CA225-025 and two other clinical trials in patients with colorectal cancer (CRC) or head and neck cancer, including Grades 3 and 4 in 6% to 17%. In EXTREME, where a cetuximab product was administered in combination with platinum-based therapy, the addition cetuximab to cisplatin and fluorouracil resulted in an increased incidence of hypomagnesemia of any grade (14%) and of Grade 3 or 4 hypomagnesemia (7%). Hypomagnesemia of any grade occurred in 4% of patients who received cetuximab, carboplatin, and fluorouracil. No patient experienced grade 3 or 4 hypomagnesemia. The onset of hypomagnesemia and accompanying electrolyte abnormalities can occur days to months after initiating ERBITUX.

Please see next page for additional information on Hypomagnesemia and Accompanying Electrolyte Abnormalities.

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ERBITUX Billing and Coding Information

CPT codes for *BRAF, KRAS,* and EGFR mutation testing modalities that may be used[4]*

ERBITUX is approved for patients with *KRAS* wild-type, EGFR-expressing mCRC as determined by an FDA-approved test. ERBITUX is also indicated, in combination with encorafenib, for the treatment of adult patients with mCRC with a *BRAF* V600E mutation, as detected by an FDA-approved test, after prior therapy.

Test Method	Code	Description
CPT codes for *BRAF* mutation testing		
Real-Time Polymerase Chain Reaction (RT-PCR)	81210	*BRAF* (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)
CPT codes for *KRAS* mutation testing		
RT-PCR	81275	*KRAS* (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13
	81276	*KRAS* (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma gene analysis; additional variant(s) (eg, codon 61, codon 146)
	81311	*NRAS*; (neuroblastoma *RAS* viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)
CPT codes for EGFR mutation testing		
RT-PCR	81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)
Immunohistochemistry	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
CPT codes for both *BRAF* and *KRAS* mutation testing		
RT-PCR	81403	Molecular pathology procedure, level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in two or more independent reactions, mutation scanning, or duplication/deletion variants of 2-5 exons)
	81405	Molecular pathology procedure, level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis)
Anatomic Pathology	88363	Examination and selection of retrieved archival (ie, previously diagnosed) tissue(s) for molecular analysis (eg, *KRAS* mutational analysis)
CPT codes for *BRAF, KRAS,* and EGFR mutation testing		
Next-generation sequencing (NGS)	81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, *ALK, BRAF, CDKN2A,* EGFR*, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET*), interrogation for sequence variants and copy number variants or rearrangements, if performed
	81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, *ALK, BRAF, CDKN2A, CEBPA, DNMT3A,* EGFR, *ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET*), interrogation for sequence variants and copy number variants or rearrangements, if performed

Coverage of *BRAF, KRAS,* and EGFR mutation testing may be limited by Medicare, Medicaid, and third-party payer benefit plans, so it is important to verify what type of services will be covered with the patient's insurer.

*Please note that this is not an all-inclusive list of available diagnostic tests and testing methods to identify *BRAF, KRAS,* and EGFR gene alterations. The laboratory is responsible for selecting the appropriate billing code for the test that is performed.

Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

SELECT IMPORTANT SAFETY INFORMATION

Hypomagnesemia and Accompanying Electrolyte Abnormalities (Continued)

- Monitor patients weekly during treatment for hypomagnesemia, hypocalcemia, and hypokalemia, and for at least 8 weeks following the completion of ERBITUX.
- Replete electrolytes as necessary.

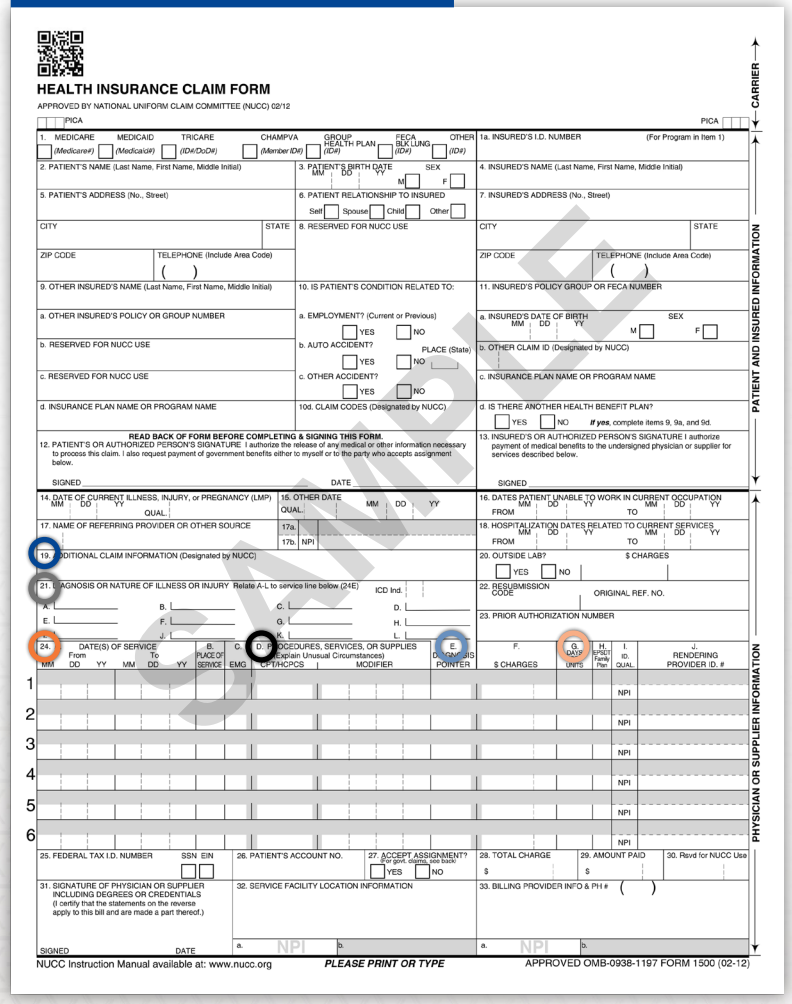
ERBITUX® CETUXIMAB
INJECTION FOR INTRAVENOUS INFUSION
100 MG/50 ML & 200 MG/100 ML VIALS

ERBITUX Billing and Coding Information

Reporting billing units in conjunction with HCPCS code J9055

- There should be **1 billing unit reported for every 10 mg of ERBITUX** that is reported using HCPCS code J9055
- For example, the use of two vials of NDC 66733-0958-23, a total of **400 mg** of ERBITUX, is reported as **40 billing units** in conjunction with HCPCS code J9055

CMS-1500 Form
(Physician's Office)


HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI
2 NPI
3 NPI
4 NPI
5 NPI
6 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

Form available at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf

Professional claims

Box 19: ADDITIONAL CLAIM INFORMATION

Box 19 of the CMS-1500 claim form (or its electronic equivalent) is frequently utilized to obtain information regarding the use of drugs. The information will vary but may include some or all of these items:

- Drug name
- NDC
- Total dose administered
- Route of administration
- Amount of drug wasted

Box 21: DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

Enter the appropriate diagnosis code in lines A-L to identify the patient's diagnosis/condition and the applicable ICD indicator to identify which ICD code version is being reported. Use the highest level of specificity.

Box 24A: DATE(S) OF SERVICE

When required by payers to provide the NDC, enter the code.

Box 24D: PROCEDURES, SERVICES, OR SUPPLIES

Enter the HCPCS or CPT® code and modifier(s) from the appropriate code set.

HCPCS

- J9055: Injection, cetuximab, 10 mg

CPT

- 96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- 96415: Chemotherapy administration, intravenous infusion technique; each additional hour
- 96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour

Box 24E: DIAGNOSIS POINTER

Enter the diagnosis code reference letter, as shown in Box 21, to relate the date of service and the procedures performed to the primary diagnosis. Enter only one reference letter per line item.

Box 24G: DAYS OR UNITS

Specify the appropriate number of service units as designated by individual payers. Check to confirm the unit of use established by each payer, as there may be variation.

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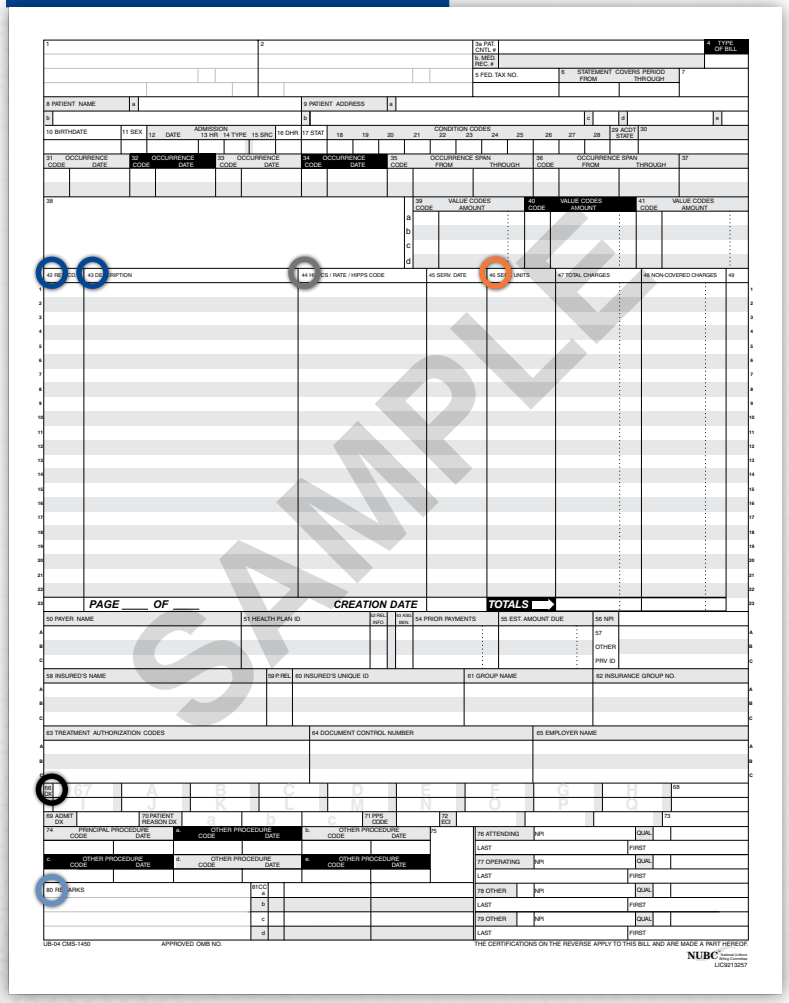
Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

ERBITUX Billing and Coding Information

CMS-1450 (UB-04) Form
(Hospital Outpatient)



Institutional claims

Form Locator (FL) 42 and 43: REVENUE CODES AND DESCRIPTION
Enter the revenue codes that correspond to HCPCS or CPT® codes outlined in FL 44. Payers may vary on revenue code requirements for each procedure/service performed.

FL 44: PRODUCT AND PROCEDURE CODING
Enter HCPCS drug code and CPT code for the administration of ERBITUX (cetuximab)

HCPCS
- J9055: Injection, cetuximab, 10 mg

CPT
- 96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- 96415: Chemotherapy administration, intravenous infusion technique; each additional hour
- 96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour

FL 46: SERVICE UNITS
Specify the appropriate number of service units as designated by individual payers. Check to confirm the unit of use established by other payers as there may be variation.

FL 66: DIAGNOSIS CODES
Enter the appropriate ICD diagnosis code(s) that correspond(s) to the type and location of the disease with which the patient has been diagnosed.

FL 80: REMARKS
To support the review and payment of the claim, include additional information as required by respective payers. This may include NDC, total dosage, and date ERBITUX was administered.

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Lilly and its agents make no guarantee regarding reimbursement for any service or item.

Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

ERBITUX® CETUXIMAB
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100 MG/50 ML & 200 MG/100 ML VIALS

ERBITUX Product Distribution

Authorized distributors

Lilly has contracted with a network of authorized distributors to provide customers access to ERBITUX. If purchasing ERBITUX directly, you may use one of the authorized distributors below.

Authorized Distributors	Contact Information
AmerisourceBergen Corporation (includes Bellco)	800-829-3132
AmerisourceBergen Specialty Group (includes ASD Specialty Healthcare Inc., Besse Medical, Oncology Supply)	800-746-6273 (ASD Specialty Healthcare, Inc.)
	800-543-2111 (Besse Medical)
	800-633-7555 (Oncology Supply)
Anda Inc.	800-331-2632
Burlington Drug	800-551-9162
Capital Wholesale	800-282-2754
Cardinal Health (includes Kinray Inc.)	800-926-3161 (Cardinal)
	888-527-6806 (Kinray)
CuraScript Specialty Distribution	877-599-7748
Dakota Drug Inc.	800-437-2018
H.D. Smith Wholesale Drug Company	866-232-1222
McKesson Corporation	800-482-3784
McKesson Specialty (includes U.S. Oncology)	800-482-6700
Miami-Luken Inc.	800-999-0302
Morris & Dickson Company Ltd.	800-388-3833
Mutual Drug	800-800-8551
Prescription Supply Inc.	800-777-0761
Rochester Drug Company	800-922-9597
Smith Drug Company	800-542-1216
Valley Wholesale Drug	800-247-6255
Value Wholesale Drug Company	800-252-3786

For more information on purchasing, dispensing, or returning Lilly products, visit **www.LillyTrade.com**.

For inquiries about product supply, contact Lilly at **1-800-821-0538, Monday-Friday, 8 AM–5 PM ET**.

Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

ERBITUX® CETUXIMAB
INJECTION FOR INTRAVENOUS INFUSION
100 MG/50 ML & 200 MG/100 ML VIALS

ERBITUX Product Specifications

Packing information

	ERBITUX 100MG	ERBITUX 200MG
NDC	6673394823	6673395823
UPC	366733948232	366733958231
Lilly Item Code	VL7676001AM	VL7709001AM
Dosage Form	Parenteral	Parenteral
Dosage Form Minimum Quantity Order	1 vial	1 vial
Carton Quantity	1 vial	1 vial
Carton Dimensions	1.77 x 1.9 x 3.3	2.43 x 4 x 1
Carton Weight	4.2 oz	6.88 oz
Case Quantity	40 cartons/case	18 cartons/case
Case Dimensions*	11.62 x 13.25 x 10.07	10.88 x 10.88 x 11.2
Case Weight	15 lbs	9.8 lbs
Pallet Quantity	48 cases/pallet	36 cases/pallet
Pallet Dimensions	48 x 42 x 49	48 x 42 x 49
Pallet Weight	~640 lbs	~400 lbs

*Uses standard corrugated boxes (RSCs).
UPC=universal product code.

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Lilly Support Services™ for Oncology: Support and Reimbursement

Find resources and programs to help support your eligible patients during treatment

The Lilly Support Services™ for Oncology is committed to helping qualified patients when they're prescribed a Lilly Oncology product. We focus on financial and coverage issues, offering resources and individualized support for eligible patients, whether they're uninsured, underinsured, or insured. Services include help with benefits verification, prior authorization, paying for medicine, and specialty pharmacy coordination.

The Lilly Support Services™ for Oncology also can provide support beyond financial assistance for certain products, and it helps patients connect with non-Lilly resources, such as therapeutic support groups for specific types of cancer.

Savings Card Program

- Supports eligible patients with Savings Card and coinsurance costs for prescribed Lilly Oncology products*
- No income eligibility requirement

For more information, visit OncologySupport.Lilly.com.

***The offer is invalid for patients whose prescription claims are eligible to be reimbursed, in whole or in part, by any governmental program.**

Insurance Support

- Eligibility determination
- Benefits investigation
- Prior authorization assistance
- Appeals information
- Specialty pharmacy coordination

Resources

- Billing and Coding information
- Payment methodologies and allowables
- Payer policy information
- Pricing information

Subject to Lilly USA, LLC's ("Lilly's") right to terminate, rescind, revoke, or amend the Lilly Oncology Infused Products Savings Card Program ("Program") and the Lilly Oncology Infused Products Savings Card ("Card") eligibility criteria, and terms and conditions, which may occur at Lilly's sole discretion, without notice, and for any reason, the Card expires and savings end on 12/31/2025. **Card savings are not available to patients without commercial drug insurance or who are enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program.** The Lilly Oncology Infused Products Savings Card applies to the following Lilly Oncology medicines ("Covered Medicine"): Cyramza® (ramucirumab) or Erbitux® (cetuximab).

MONTHLY AND ANNUAL MAXIMUM SAVINGS: You must (a) have commercial drug insurance that covers your prescribed Covered Medicine but does not cover the full cost and (b) a prescription for an approved use consistent with FDA-approved product labeling to pay as little as $25 for each infusion of your Covered Medicine. The Program will cover your co-pay or coinsurance for your prescribed Covered Medicine less $25, up to a maximum monthly savings of up to wholesale acquisition cost plus usual and customary fees and a separate maximum annual savings of up to $25,000 per calendar year. Card may be used for a maximum of up to 12 infusions per calendar year. The Program may provide support for infusions with a date of service that falls within 120 days prior to the date the enrollment form is received by the Program. To receive Program savings, your healthcare provider must submit a claim for coverage to your medical insurance provider. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason. Card expires and savings end on 12/31/2025.

ADDITIONAL TERMS AND CONDITIONS:

You are responsible for any applicable taxes, fees, and any amount that exceeds the monthly or annual maximum savings. Participation in the program requires a valid patient HIPAA authorization upon enrollment in the Program. This Card may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Lilly Oncology Infused Products Savings Card Program may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at https://www.oncologysupport.lilly.com. Card void where prohibited by law. **THIS CARD IS NOT INSURANCE**.

For more information about the Lilly Support Services™ for Oncology, call 1-800-545-5979, Monday–Friday, 8 AM–10 PM ET, or visit OncologySupport.Lilly.com.

Lilly
A MEDICINE COMPANY

IMPORTANT SAFETY INFORMATION FOR ERBITUX

WARNING: INFUSION REACTIONS AND CARDIOPULMONARY ARREST

Infusion Reactions - ERBITUX can cause serious and fatal infusion reactions. Severe (Grades 3 and 4) infusion reactions occurred in 2.2% of patients receiving ERBITUX in clinical trials.

- The risk of anaphylactic reactions may be increased in patients with a history of tick bites, red meat allergy, or in the presence of IgE antibodies directed against galactose-α-1,3-galactose (alpha-gal). Consider testing patients for alpha-gal IgE antibodies using FDA-cleared methods prior to initiating ERBITUX. Negative results for alpha-gal antibodies do not rule out the risk of severe infusion reactions.
- Approximately 90% of the severe infusion reactions occurred with the first infusion of ERBITUX despite premedication with antihistamines.
  - Serious infusion reactions, requiring immediate medical intervention, included symptoms of rapid onset of airway obstruction (bronchospasm, stridor, hoarseness), hypotension, shock, loss of consciousness, myocardial infarction, and/or cardiac arrest. Immediately interrupt and permanently discontinue ERBITUX infusion for serious infusion reactions.
  - Caution must be exercised with every ERBITUX infusion as infusion reactions may occur during or several hours following completion of the infusion.
  - Premedicate with a histamine-1 (H1) receptor antagonist as recommended.
  - Monitor patients for at least 1 hour following each ERBITUX infusion in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis. In patients requiring treatment for infusion reactions, monitor for more than 1 hour to confirm resolution of the reaction. Interrupt the infusion and upon recovery, resume the infusion at a slower rate or permanently discontinue ERBITUX based on severity.

Cardiopulmonary Arrest - ERBITUX can cause cardiopulmonary arrest. Cardiopulmonary arrest or sudden death occurred in 2% of 208 patients with squamous cell carcinoma of the head and neck receiving radiation therapy and ERBITUX in BONNER. In 3 patients with prior history of coronary artery disease, death occurred 27, 32, and 43 days respectively after the last dose of ERBITUX. One patient with no prior history of coronary artery disease died one day after the last dose of ERBITUX. In EXTREME, fatal cardiac disorders and/or sudden death occurred in 3% of the 219 patients with squamous cell carcinoma of the head and neck treated with a cetuximab product in combination with platinum-based therapy and fluorouracil.

- Carefully consider the use of ERBITUX with radiation therapy, or with platinum-based therapy with fluorouracil, in head and neck cancer patients with a history of coronary artery disease, congestive heart failure, or arrhythmias.
- Closely monitor serum electrolytes, including serum magnesium, potassium, and calcium, during and after ERBITUX therapy.

Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

ERBITUX® CETUXIMAB
INJECTION FOR INTRAVENOUS INFUSION
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IMPORTANT SAFETY INFORMATION FOR ERBITUX (CONTINUED)

Pulmonary Toxicity

- ERBITUX can cause interstitial lung disease (ILD). ILD, which was fatal in one case, occurred in <0.5% of 1570 patients receiving ERBITUX in clinical trials. Monitor patients for signs and symptoms of pulmonary toxicity. Interrupt or permanently discontinue ERBITUX for acute onset or worsening of pulmonary symptoms. Permanently discontinue ERBITUX for confirmed ILD.

Dermatologic Toxicities

- ERBITUX can cause dermatologic toxicities, including acneiform rash, skin drying and fissuring, paronychial inflammation, infectious sequelae (e.g., S. aureus sepsis, abscess formation, cellulitis, blepharitis, conjunctivitis, keratitis/ulcerative keratitis with decreased visual acuity, cheilitis), and hypertrichosis
  - Acneiform rash occurred in 82% of the 1373 patients who received ERBITUX across clinical trials. Severe (Grades 3 or 4) acneiform rash occurred in 10% of patients. Acneiform rash usually developed within the first 2 weeks of therapy; the rash lasted more than 28 days after stopping ERBITUX in most patients.
  - Life-threatening and fatal bullous mucocutaneous disease with blisters, erosions, and skin sloughing has been observed in patients who received ERBITUX. It could not be determined whether these mucocutaneous adverse reactions were directly related to EGFR inhibition or to idiosyncratic immune-related effects (e.g., Stevens-Johnson syndrome or toxic epidermal necrolysis).
  - Monitor patients receiving ERBITUX for dermatologic toxicities and infectious sequelae.
  - Sun exposure may exacerbate these effects. Instruct patients to limit sun exposure during ERBITUX therapy.
  - Withhold, reduce dose or permanently discontinue ERBITUX based on severity of acneiform rash or mucocutaneous disease.

Risks Associated with Use in Combination with Radiation and Cisplatin

- ERBITUX is not indicated for the treatment of SCCHN in combination with radiation and cisplatin.
- In a controlled study, 940 patients with locally advanced SCCHN were randomized 1:1 to receive either ERBITUX in combination with radiation therapy and cisplatin, or radiation therapy and cisplatin alone. The addition of ERBITUX resulted in an increase in the incidence of Grade 3 and 4 mucositis, radiation recall syndrome, acneiform rash, cardiac events, and electrolyte disturbances compared to radiation and cisplatin alone.
- Adverse reactions with fatal outcome were reported in 4% of patients in the ERBITUX combination arm and 3% in the control arm.
- In the ERBITUX arm, 2% experienced myocardial ischemia compared to 0.9% in the control arm.
- The addition of ERBITUX to radiation and cisplatin did not improve progression-free survival (the primary endpoint).

Hypomagnesemia and Accompanying Electrolyte Abnormalities

- ERBITUX can cause hypomagnesemia. Hypomagnesemia occurred in 55% of 365 patients receiving ERBITUX in study CA225-025 and two other clinical trials in patients with colorectal cancer (CRC) or head and neck cancer, including Grades 3 and 4 in 6% to 17%. In EXTREME, where a cetuximab product was administered in combination with platinum-based therapy, the addition cetuximab to cisplatin and fluorouracil resulted in an increased incidence of hypomagnesemia of any grade (14%) and of Grade 3 or 4 hypomagnesemia (7%). Hypomagnesemia of any grade occurred in 4% of patients who received cetuximab, carboplatin, and fluorouracil. No patient experienced grade 3 or 4 hypomagnesemia. The onset of hypomagnesemia and accompanying electrolyte abnormalities can occur days to months after initiating ERBITUX.
  - Monitor patients weekly during treatment for hypomagnesemia, hypocalcemia, and hypokalemia, and for at least 8 weeks following the completion of ERBITUX.
  - Replete electrolytes as necessary.

Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

ERBITUX® CETUXIMAB
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IMPORTANT SAFETY INFORMATION FOR ERBITUX (CONTINUED)

Increased Tumor Progression, Increased Mortality, or Lack of Benefit in Patients with Ras-Mutant mCRC

- ERBITUX is not indicated for the treatment of patients with CRC that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either K-Ras or N-Ras and hereafter referred to as "Ras" or when the Ras status is unknown.
- Retrospective subset analyses of Ras-mutant and wild-type populations across several randomized clinical trials, including CRYSTAL, were conducted to investigate the role of Ras mutations on the clinical effects of anti-EGFR-directed monoclonal antibodies. Use of cetuximab in patients with Ras mutations resulted in no clinical benefit with treatment related toxicity. Confirm Ras mutation status in tumor specimens prior to initiating ERBITUX.

Embryo-Fetal Toxicity

- Based on animal data and its mechanism of action, ERBITUX can cause fetal harm when administered to a pregnant woman. There are no available data for ERBITUX exposure in pregnant women. In an animal reproduction study, intravenous administration of cetuximab once weekly to pregnant cynomolgus monkeys during the period of organogenesis resulted in an increased incidence of embryolethality and abortion. Disruption or depletion of EGFR in animal models results in impairment of embryo-fetal development including effects on placental, lung, cardiac, skin, and neural development. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ERBITUX and for 2 months after the last dose of ERBITUX. Verify pregnancy status in females of reproductive potential prior to initiating ERBITUX.

Adverse Reactions

- The most common adverse reactions (all grades; incidence ≥25%) seen in patients with carcinomas of the head and neck receiving ERBITUX in combination with radiation therapy (n=208) versus radiation alone (n=212) (BONNER) were acneiform rash (87% vs 10%), radiation dermatitis (86% vs 90%), weight loss (84% vs 72%), asthenia (56% vs 49%), nausea (49% vs 37%), increased alanine transaminase (43% vs 21%), increased aspartate transaminase (38% vs 24%), increased alkaline phosphatase (33% vs 24%), fever (29% vs 13%), emesis (29% vs 23%), pharyngitis (26% vs 19%) and dehydration (25% vs 19%). The most common grade 3 and 4 adverse reactions for ERBITUX in combination with radiation therapy (≥10%) versus radiation alone included: radiation dermatitis (23% vs 18%), acneiform rash (17% vs 1%), and weight loss (11% vs 7%). The overall incidence of late radiation toxicities (any grade) was higher for patients receiving ERBITUX in combination with radiation therapy, versus radiation therapy alone. The following sites were affected: salivary glands (65% vs 56%), larynx (52% vs 36%), subcutaneous tissue (49% vs 45%), mucous membrane (48% vs 39%), esophagus (44% vs 35%), skin (42% vs 33%). The incidence of Grade 3 or 4 late radiation toxicities was similar between radiation therapy alone and the ERBITUX with radiation treatment groups.
- The most common adverse reactions (all grades; incidence ≥25%) seen in patients with carcinomas of the head and neck receiving a cetuximab product in combination with platinum-based therapy and fluorouracil (CT) (n=219) versus CT alone (n=215) (EXTREME) were acneiform rash (70% vs 2%), nausea (54% vs 47%), infection (44% vs 27%), rash (28% vs 2%), diarrhea (26% vs 16%) and anorexia (25% vs 14%). The most common grade 3 and 4 adverse reaction for a cetuximab product in combination with CT (≥10%) versus CT alone was infection (11% vs 8%). Because ERBITUX provides approximately 22% higher exposure relative to the cetuximab product used in EXTREME, the data provided above may underestimate the incidence and severity of adverse reactions anticipated with ERBITUX for this indication. However, the tolerability of the recommended dose is supported by safety data from additional studies of ERBITUX.
- The most common adverse reactions (all grades; incidence ≥25%) seen in patients with K-Ras wild-type, EGFR-expressing mCRC treated with a cetuximab product in combination with FOLFIRI (n=317) versus FOLFIRI alone (n=350) (CRYSTAL) were acne-like rash (86% vs 13%), diarrhea (66% vs 60%), neutropenia (49% vs 42%), rash (44% vs 4%), stomatitis (31% vs 19%), anorexia (30% vs 23%), dermatitis acneiform (26% vs <1%) and pyrexia (26% vs 14%). The most common grade 3 and 4 adverse reactions (≥10%) included: neutropenia (31% vs 24%), acne-like rash (18% vs <1%), and diarrhea (16% vs 10%). ERBITUX provides approximately 22% higher exposure compared to the cetuximab product used in CRYSTAL; however, the safety data from CRYSTAL is consistent in incidence and severity of adverse reactions with those seen for ERBITUX in this indication.

Please see Important Safety Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest, on pages 17-20. Click here for full Prescribing Information.

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IMPORTANT SAFETY INFORMATION FOR ERBITUX (CONTINUED)

Adverse Reactions (Continued)

- The most common adverse reactions (all grades; incidence ≥25%) seen in patients with K-Ras wild-type, EGFR-expressing mCRC treated with ERBITUX + best supportive care (BSC) (n=118) versus BSC alone (n=124) (CA225-025) were rash/desquamation (95% vs 21%), fatigue (91% vs 79%), nausea (64% vs 50%), pain-other (59% vs 37%), dry skin (57% vs 15%), constipation (53% vs 38%), dyspnea (49% vs 44%), pruritus (47% vs 11%), neuropathy-sensory (45% vs 38%), diarrhea (42% vs 23%), vomiting (40% vs 26%), headache (38% vs 11%), infection without neutropenia (38% vs 19%), other-dermatology (35% vs 7%), stomatitis (32% vs 10%), nail changes (31% vs 4%), cough (30% vs 19%), insomnia (27% vs 13%) and fever (25% vs 16%). The most common grade 3 and 4 adverse reactions (≥10%) included: fatigue (31% vs 29%), pain-other (18% vs 10%), rash/desquamation (16% vs 1%), dyspnea (16% vs 13%), other-gastrointestinal (12% vs 5%), and infection without neutropenia (11% vs 5%).
- The most common adverse reactions (all grades) seen in patients with EGFR-expressing recurrent mCRC (n=354) treated with ERBITUX plus irinotecan in clinical trials (CP02-9923 and BOND) were acneiform rash (88%), asthenia/malaise (73%), diarrhea (72%), and nausea (55%). The most common grade 3-4 adverse reactions included: diarrhea (22%), leukopenia (17%), asthenia/malaise (16%), and acneiform rash (14%).
- The most common adverse reactions (all grades; incidence ≥25%) seen in patients with BRAF V600E mutation-positive mCRC treated with ERBITUX in combination with encorafenib (N=216) versus ERBITUX with irinotecan or ERBITUX with FOLFIRI (N=193) (BEACON) were fatigue (51% vs 50%), nausea (34% vs 41%), diarrhea (33% vs 48%), dermatitis acneiform (32% vs 43%), abdominal pain (30% vs 32%), decreased appetite (27% vs 27%), arthralgia (27% vs 3%) and rash (26% vs 26%). Other clinically important adverse reactions occurring in <10% of patients who received ERBITUX in combination with encorafenib were pancreatitis. The most common laboratory abnormalities (all grades; incidence ≥20%) seen in patients receiving ERBITUX in combination with encorafenib versus ERBITUX with irinotecan or ERBITUX with FOLFIRI (BEACON) were anemia (34% vs 48%) and lymphopenia (24% vs 35%).

Use in Specific Populations

- **Lactation:** There is no information regarding the presence of ERBITUX in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG antibodies can be excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from ERBITUX, advise women not to breastfeed during treatment with ERBITUX and for at least 2 months after the last dose of ERBITUX.
- **Pediatric Use:** The safety and effectiveness of ERBITUX in pediatric patients have not been established. No new safety signals were identified in pediatric patients when ERBITUX in combination with irinotecan was administered in an open-label, single-arm dose-finding study in 27 patients with refractory solid tumors aged 1 to 12 years old and in 19 patients aged 13 to 18 years old.
- **Geriatric Use:** In SCCHN clinical studies of ERBITUX there were insufficient number of patients >65 years of age to determine whether they respond differently from younger patients.

Please see full Prescribing Information for ERBITUX, including Boxed Warning regarding infusion reactions and cardiopulmonary arrest.

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