

Erbitux® (Cetuximab)

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[↪ Terms and Conditions](#)

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Policy Summary

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Overview

Cetuximab is a monoclonal antibody produced by recombinant DNA technology in a murine cell culture. This antibody binds specifically to the epidermal growth factor receptor (EGFR, HER1, c-ErbB-1) on both normal and tumor cells resulting in inhibition of cell growth and causing cell death.

Guidelines

As published in [CMS Program Integrity Manual, Section 13.5.1](#), in order to be covered under Medicare, a service shall be reasonable and necessary.

Drugs and biologicals must be determined to meet the statutory definition under the statute [§1861\(t\) \(1\)](#).

[Medicare Benefit Policy Manual – Pub. 100-02, Chapter 15, Section 50](#), describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals;
- They are of the type that are not usually self-administered by the patients who take them;
- They meet all the general requirements for coverage of items as incident to a physician's services;
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- They are not excluded as immunizations; and
- They have not been determined by the FDA to be less than effective.

Coverage for medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia listed below.

- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- Thomson Micromedex DrugDex
- Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

The compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium.

Note: It is not appropriate to bill for services that are not covered (as described by this entire policy guideline) as if they are covered. When billing for non-covered services, use the appropriate modifier.

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge will be excluded (i.e., for both the drug and its administration). Also excluded from payment is any charge for other services (such as office visits) which are primarily for the purpose of administering a non-covered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals and cancer chemotherapeutic agents approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling.

Therefore, payment may be made for an FDA-approved chemotherapeutic drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the contractor determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

There are many reasons to consider an unlabeled use for a cancer chemotherapy agent. Some of these are:

- Drugs may be effective for many other cancers in addition to the ones that were considered in the primary drug labeling.
- Many chemotherapeutic agents are given in combinations. Any one of the drugs in the combination may not have been approved in the initial labeling of the products. In addition the combination of effective chemotherapeutic agents changes over time.
- Cancer chemotherapeutic agents are always changing and improving over time.
- Oncologists are often left with few approved treatment options if initial treatment regimens have failed.

Coverage

Cetuximab (Erbix[®]) is FDA approved for the following indications:

Head and Neck Cancer

- Locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy.
- Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with fluorouracil.
- Recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy.

Colorectal Cancer

K-Ras wild-type, EGFR-expressing, metastatic colorectal cancer as determined by an FDA-approved test

- In combination with FOLFIRI 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.

Refer also to the NCCN Compendium® for additional off-label indications.

Limitations

Erbix® is not indicated for treatment of Ras-mutant colorectal cancer or when the results of the Ras mutation tests are unknown.

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this policy guideline. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

The medical record must include the following information:

- The name of the drug or biological administered;
- The route of administration;
- The dosage (e.g., mgs, mcgs, cc's or IU's); and
- The duration of the administration (for CPT codes that are time based).

Applicable Codes

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J9055	Injection, cetuximab, 10 mg

Modifier	Description
KX	Requirements specified in the medical policy have been met

Diagnosis Code	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

Diagnosis Code	Description
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
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
C05.2	Malignant neoplasm of uvula (Deleted 09/09/2020)
C05.8	Malignant neoplasm of overlapping sites of palate (Deleted 09/09/2020)
C05.9	Malignant neoplasm of palate, unspecified (Deleted 09/09/2020)
C06.0	Malignant neoplasm of cheek mucosa
C06.1	Malignant neoplasm of vestibule of mouth (Deleted 09/09/2020)
C06.2	Malignant neoplasm of retro-molar 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
C07	Malignant neoplasm of parotid gland (Deleted 09/09/2020)
C08.0	Malignant neoplasm of submandibular gland (Deleted 09/09/2020)
C08.1	Malignant neoplasm of sublingual gland (Deleted 09/09/2020)
C08.9	Malignant neoplasm of major salivary gland, unspecified (Deleted 09/09/2020)
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

Diagnosis Code	Description
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
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified site
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
C21.0	Malignant neoplasm of anus, unspecified (Deleted 09/09/2020)
C21.1	Malignant neoplasm of anal canal (Deleted 09/09/2020)
C21.2	Malignant neoplasm of cloacogenic zone (Deleted 09/09/2020)
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C30.0	Malignant neoplasm of nasal cavity
C30.1	Malignant neoplasm of middle ear (Deleted 09/09/2020)
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C31.2	Malignant neoplasm of frontal sinus (Deleted 09/09/2020)
C31.3	Malignant neoplasm of sphenoid sinus (Deleted 09/09/2020)
C31.8	Malignant neoplasm of overlapping sites of accessory sinuses (Deleted 09/09/2020)
C31.9	Malignant neoplasm of accessory sinus, unspecified (Deleted 09/09/2020)
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

Diagnosis Code	Description
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
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
C44.01	Basal cell carcinoma of skin of lip (Deleted 09/09/2020)
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
C44.40	Unspecified malignant neoplasm of scalp and skin of neck (Deleted 09/09/2020)
C44.41	Basal cell carcinoma of scalp and skin of neck (Deleted 09/09/2020)
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

Diagnosis Code	Description
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, site unspecified
C47.0	Malignant neoplasm of peripheral nerves of head, face, and neck (Deleted 09/09/2020)
C49.0	Malignant neoplasm of connective and other soft tissue of head, face, and neck (Deleted 09/09/2020)
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
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C69.91	Malignant neoplasm of unspecified site of right eye (Deleted 09/09/2020)
C69.92	Malignant neoplasm of unspecified site of left eye (Deleted 09/09/2020)
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
C78.89	Secondary malignant neoplasm of other digestive organs
C79.31	Secondary malignant neoplasm of brain (Deleted 09/09/2020)
C79.89	Secondary malignant neoplasm of other specified sites (Deleted 09/09/2020)
C7B.1	Secondary Merkel cell carcinoma (Deleted 09/09/2020)
C80.0	Disseminated malignant neoplasm, unspecified (Deleted 09/09/2020)
C80.1	Malignant (primary) neoplasm, unspecified (Deleted 09/09/2020)
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site (Deleted 09/09/2020)
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck (Deleted 09/09/2020)
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes (Deleted 09/09/2020)
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes (Deleted 09/09/2020)
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb (Deleted 09/09/2020)
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb (Deleted 09/09/2020)
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes (Deleted 09/09/2020)
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen (Deleted 09/09/2020)
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites (Deleted 09/09/2020)
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites (Deleted 09/09/2020)
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site (Deleted 09/09/2020)
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck (Deleted 09/09/2020)
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes (Deleted 09/09/2020)

Diagnosis Code	Description
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes (Deleted 09/09/2020)
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb (Deleted 09/09/2020)
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb (Deleted 09/09/2020)
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes (Deleted 09/09/2020)
C81.27	Mixed cellularity Hodgkin lymphoma, spleen (Deleted 09/09/2020)
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites (Deleted 09/09/2020)
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites (Deleted 09/09/2020)
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site (Deleted 09/09/2020)
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck (Deleted 09/09/2020)
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes (Deleted 09/09/2020)
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes (Deleted 09/09/2020)
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb (Deleted 09/09/2020)
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb (Deleted 09/09/2020)
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes (Deleted 09/09/2020)
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen (Deleted 09/09/2020)
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites (Deleted 09/09/2020)
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites (Deleted 09/09/2020)
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site (Deleted 09/09/2020)
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes (Deleted 09/09/2020)
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes (Deleted 09/09/2020)
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb (Deleted 09/09/2020)
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb (Deleted 09/09/2020)
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes (Deleted 09/09/2020)
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen (Deleted 09/09/2020)
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites (Deleted 09/09/2020)
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites (Deleted 09/09/2020)
C81.90	Hodgkin lymphoma, unspecified, unspecified site (Deleted 09/09/2020)
C81.91	Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck (Deleted 09/09/2020)
C81.92	Hodgkin lymphoma, unspecified, intrathoracic lymph nodes (Deleted 09/09/2020)
C81.93	Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes (Deleted 09/09/2020)
C81.94	Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb (Deleted 09/09/2020)
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb (Deleted 09/09/2020)
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes (Deleted 09/09/2020)
C81.97	Hodgkin lymphoma, unspecified, spleen (Deleted 09/09/2020)
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites (Deleted 09/09/2020)
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites (Deleted 09/09/2020)
D00.01	Carcinoma in situ of labial mucosa and vermilion border (Deleted 09/09/2020)
D00.02	Carcinoma in situ of buccal mucosa (Deleted 09/09/2020)
D00.03	Carcinoma in situ of gingiva and edentulous alveolar ridge (Deleted 09/09/2020)
D00.04	Carcinoma in situ of soft palate (Deleted 09/09/2020)

Diagnosis Code	Description
D00.05	Carcinoma in situ of hard palate (Deleted 09/09/2020)
D00.06	Carcinoma in situ of floor of mouth (Deleted 09/09/2020)
D00.07	Carcinoma in situ of tongue (Deleted 09/09/2020)
D00.08	Carcinoma in situ of pharynx (Deleted 09/09/2020)
D04.0	Carcinoma in situ of lip (Deleted 09/09/2020)
D04.39	Carcinoma in situ of skin of other parts of face (Deleted 09/09/2020)
D04.4	Carcinoma in situ of skin of scalp and neck (Deleted 09/09/2020)
D37.01	Neoplasm of uncertain behavior of lip
D37.02	Neoplasm of uncertain behavior of tongue
D37.04	Neoplasm of uncertain behavior of the minor salivary glands (Deleted 09/09/2020)
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
Z85.20	Personal history of malignant neoplasm of unspecified respiratory organ (Deleted 09/09/2020)
Z85.21	Personal history of malignant neoplasm of larynx
Z85.22	Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
Z85.49	Personal history of malignant neoplasm of other male genital organs
Z85.71	Personal history of Hodgkin lymphoma (Deleted 09/09/2020)
Z85.810	Personal history of malignant neoplasm of tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx
Z85.819	Personal history of malignant neoplasm of unspecified site of lip, oral cavity, and pharynx
Z85.820	Personal history of malignant melanoma of skin (Deleted 09/09/2020)
Z85.821	Personal history of Merkel cell carcinoma (Deleted 09/09/2020)
Z85.828	Personal history of other malignant neoplasm of skin

Definitions

Off-Label Drug Use: An off-label/unlabeled use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information. An indication is defined as a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration and frequency of administration, and population to whom the drug would be administered. Drugs used for indications other than those in the approved labeling may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice. Determinations as to whether medication is reasonable and necessary for an individual patient are made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

References

CMS National Coverage Determination (NCD)

[NCD 110.17 Anti-Cancer Chemotherapy for Colorectal Cancer](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses	A52855 Billing and Coding: Drugs and Biologicals	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L37205 Chemotherapy Drugs and their Adjuncts	N/A	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
N/A	A53049 Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
N/A	A58113 Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen	CGS	KY, OH	KY, OH
N/A	A52953 Chemotherapy Administration	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A52991 Billing and Coding: Chemotherapy Administration	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L34093 Chemotherapy and Biologicals Retired 06/07/2020	A57234 Billing and Coding: Cetuximab; Erbitux -J9055 Retired 06/07/2020	CGS	KY, OH	KY, OH
L33278 Cetuximab (Erbitux®) Retired 11/15/2019	N/A	First Coast	FL, PR, VI	FL, PR, VI

CMS Benefit Policy Manual

[Chapter 15: § 50 Drugs and Biologicals](#)

Other(s)

[Erbitux® Prescribing Information](#)

[CMS Program Integrity Manual, § 13.5.1 Reasonable and Necessary Provisions in LCDs](#)

[Correct Coding Initiative - Medicare Contractor Beneficiary and Provider Communications Manual, Chapter 5](#)

[Medicare Managed Care Manual Chapter 4: § 10.7 Clinical Trials](#)

[NCCN Drugs & Biologics Compendium](#)

Social Security Act (Title XVIII) Standard References, Sections:

- [1862\(a\)\(1\)\(A\) Medically Reasonable & Necessary](#)
- [1862\(a\)\(1\)\(D\) Investigational or Experimental](#)

Erbitux® (Cetuximab)

UnitedHealthcare Medicare Advantage Policy Guideline

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Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	<p>Template Update</p> <ul style="list-style-type: none"> • Reformatted policy; transferred content to new template
09/09/2020	<p>Policy Summary</p> <p><i>Overview</i></p> <ul style="list-style-type: none"> • Revised language to indicate: <ul style="list-style-type: none"> ○ Cetuximab is a monoclonal antibody produced by recombinant DNA technology in a murine cell culture ○ This antibody binds specifically to the epidermal growth factor receptor (EGFR, HER1, c-ErbB-1) on both normal and tumor cells resulting in inhibition of cell growth and causing cell death • Relocated language pertaining to FDA approved and off-label indications (see Coverage section) • Removed language pertaining to non-small cell lung cancer (no CMS reference available) <p><i>Guidelines</i></p> <ul style="list-style-type: none"> • Removed content addressed in the referenced Medicare Benefit Policy Manual – Pub. 100-02, Chapter 15, Section 50 <p><i>Chemotherapy Administration</i></p> <ul style="list-style-type: none"> • Removed content addressed in the Local Coverage Article (LCA) titled <i>Chemotherapy Administration (A52953)</i>; refer to the <i>References</i> section of the policy <p><i>Coding Guidelines</i></p> <ul style="list-style-type: none"> • Removed instruction on appropriate code reporting <p><i>Coverage</i></p> <ul style="list-style-type: none"> • Added language (relocated from the <i>Overview</i> section) to indicate: <ul style="list-style-type: none"> ○ Cetuximab (Erbix[®]) is FDA approved for the following indications: <ul style="list-style-type: none"> ▪ Head and Neck Cancer <ul style="list-style-type: none"> – Locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy – Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with fluorouracil – Recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy ▪ Colorectal Cancer (K-Ras wild-type, EGFR-expressing, metastatic colorectal cancer as determined by an FDA-approved test) <ul style="list-style-type: none"> – In combination with FOLFIRI 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 ○ Refer also to the NCCN Compendium[®] for additional off-label indications <p><i>Limitations</i></p> <ul style="list-style-type: none"> • Added language (relocated from the <i>Overview</i> section) to indicate Erbix[®] is not indicated for treatment of Ras-mutant colorectal cancer or when the results of the Ras mutation tests are unknown <p><i>Documentation Requirements</i></p> <ul style="list-style-type: none"> • Revised language to indicate:

Date	Summary of Changes
	<ul style="list-style-type: none"> ○ The patient’s medical record must contain documentation that fully supports the medical necessity for services included within this policy guideline ○ This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures ○ The medical record must include the following information: <ul style="list-style-type: none"> ▪ The name of the drug or biological administered; ▪ The route of administration; ▪ The dosage (e.g., mgs, mcgs, cc's or IU's); and ▪ The duration of the administration (for CPT codes that are time based) <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Removed Modifier GZ ● Added notation to indicate ICD-10 diagnosis codes C05.2, C05.8, C05.9, C06.1, C07, C08.0, C08.1, C08.9, C21.0, C21.1, C21.2, C30.1, C31.2, C31.3, C31.8, C31.9, C44.01, C44.40, C44.41, C47.0, C49.0, C69.91, C69.92, C79.31, C79.89, C7B.1, C80.0, C80.1, C81.10, C81.11, C81.12, C81.13, C81.14, C81.15, C81.16, C81.17, C81.18, C81.19, C81.20, C81.21, C81.22, C81.23, C81.24, C81.25, C81.26, C81.27, C81.28, C81.29, C81.30, C81.31, C81.32, C81.33, C81.34, C81.35, C81.36, C81.37, C81.38, C81.39, C81.40, C81.42, C81.43, C81.44, C81.45, C81.46, C81.47, C81.48, C81.49, C81.90, C81.91, C81.92, C81.93, C81.94, C81.95, C81.96, C81.97, C81.98, C81.99, D00.01, D00.02, D00.03, D00.04, D00.05, D00.06, D00.07, D00.08, D04.0, D04.39, D04.4, D37.04, Z85.20, Z85.71, Z85.820, and Z85.821 were “deleted Sep. 9, 2020” <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>References</i> section to reflect the most current information ● Archived previous policy version MPG101.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).