INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview
Cetuximab or brand name Erbitux is a recombinant, human/mouse chimeric monoclonal antibody that binds specifically to the extracellular domain of the human epidermal growth factor receptor (EGFR). Cetuximab is composed of the Fv regions of a murine and-EGFR antibody with human IgG1 heavy and kappa light chain constant regions and has an approximate molecular weight of 152 kDa. Cetuximab is produced in mammalian (murine myeloma) cell culture. Cetuximab is FDA approved for injection for the following indications.

Colorectal Cancer
- K-Ras mutation-negative (wild-type), EGFR-expressing, metastatic colorectal cancer as determined by FDA-approved tests. Limitation of Use: Erbitux is not indicated for treatment of K-Ras mutation-positive colorectal cancer.
  - Cetuximab is indicated for use in combination with FOLFIRI for first-line treatment (irinotecan, 5-fluorouracil, leucovorin) with K-ras mutation-negative (wild-type), EGFR-expressing metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use. FDA also approved the Therascreen KRAS RGQ PCR Kit (QIAGEN Manchester, Ltd) concurrent with this cetuximab approval.
  - Used in combination with irinotecan, cetuximab is indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma in patients who are refractory to irinotecan-based chemotherapy.

Eributux® (Cetuximab)
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Administered as a single agent, cetuximab is indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma after failure of both irinotecan and oxaliplatin-based regimens or in patients who are intolerant to irinotecan-based chemotherapy.

Medicare considers cetuximab (Erbitux) medically necessary for treatment of beneficiaries with metastatic colorectal cancer and considers analysis of K-ras (KRAS) mutation in codon 12 or 13 medically necessary for predicting non-response to cetuximab in the treatment of metastatic colorectal cancer. Use of Erbitux is not recommended for the treatment of colorectal cancer with these mutations.

**Head and Neck Cancer**

- Used in combination with radiation therapy, cetuximab is indicated for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck.
- As a single agent, cetuximab is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck for whom prior platinum-based therapy has failed.
- Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-FU.

Medicare will consider the use of Erbitux (cetuximab) as medically reasonable and necessary for the FDA approved uses as well as the following off-labeled indication:

**Non-Small Cell Lung Cancer (NSCLC)**

First line therapy for reoccurrence or metastasis in combination with vinorebine and cisplatin in patients with performance status 0-2 (ECOG Performance Status)

**Guidelines**

This reimbursement policy supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for chemotherapeutic drug and biological services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this policy. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for chemotherapeutic drug and biological services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies regarding chemotherapeutic drug and biological services are found in the following Internet-Only Manuals (IOMs) published on the CMS website:

- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50.
- Correct Coding Initiative - Medicare Contractor Beneficiary and Provider Communications Manual - Pub. 100-09, Chapter 5.
- Social Security Act (Title XVIII) Standard References, Sections:
  - 1862(a)(1)(A) Medically Reasonable & Necessary
  - 1862(a)(1)(D) Investigational or Experimental
  - 1833(e) Incomplete Claim

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.

In reading this document, please note that there is a difference between the section of the statute which defines the overall Medicare benefit for coverage of drugs and biologicals, and the section of the statute which states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury. This policy gives information about the overall Medicare benefit for coverage of drugs and biologicals.

**Note:** This policy does not describe drug and biological coverage under the Medicare Part D benefit.

It is not appropriate to bill UnitedHealthcare for services that are not covered (as described by this entire reimbursement policy) as if they are covered. When billing for non-covered services, use the appropriate modifier (see “Coding Guidelines” section in this policy). This policy explains the coverage criteria for drugs and biologicals used in
the treatment of cancer. The policy has been promulgated to establish the clinical conditions for which the included
chemotherapeutic drug is considered to be medically reasonable and necessary and thus, covered by Medicare.

Unless certain specified conditions are met, UnitedHealthcare will not reimburse for unlabeled use of non-self-
administered drugs, since unlabeled use of the drug is considered an investigational use. Medicare is not allowed to
pay for investigational treatments. However, FDA-approved drugs used for indications other than what is indicated on
the official label may be covered by UnitedHealthcare when Medicare determines the use to be medically accepted,
taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of
medical practice. In the case of unlabeled use for anti-cancer drugs, the conditions for Medicare coverage and
reimbursement have been especially well outlined.

**Note:** This reimbursement policy imposes diagnosis limitations that support diagnosis to procedure code automated
denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in
this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all
existing CMS national coverage determinations, and all Medicare payment rules.

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. UnitedHealthcare shall consider a service to be reasonable and necessary if we
determine that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of
  service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered
  reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of
  whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the
    patient's condition or to improve the function of a malformed body member.
  - Furnished in a setting appropriate to the patient's medical needs and condition.
  - Ordered and furnished by qualified personnel.
  - One that meets, but does not exceed, the patient's medical needs.
  - At least as beneficial as an existing and available medically appropriate alternative.

Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t) (1), payment
may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of
the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information
(USD-DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, except for those drugs and
biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI
does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information
developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for
generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a
necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not
enough. Rather, the product must also meet all other program requirements to be determined to be a drug or
biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the
therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug
compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established
procedure by the professional organization responsible for revision of the compendium.

Drugs that are usually self-administered by the patient, such as those in pill form, or are used for self-injection, are
generally not covered by Part B. However, there are a limited number of self-administered drugs that are covered
because the Medicare statute explicitly provides coverage. Examples of drugs that are usually self-administered by the
patient and are covered include: blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for
dialysis patients, and osteoporosis drugs for certain homebound patients. (See [Self-Administered Drug(s) (SAD)]
policy.)

Generally, when a physician gives a patient pills or other oral medication, these drugs are excluded from coverage
since the form of the drug is self-administered. Similarly, if a physician gives a patient an injection that is usually self-
injected this drug is excluded from coverage, unless administered to the patient in an emergency situation.

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or
biological must be of a form that cannot be self-administered and must be administered by a physician or by auxiliary
personnel employed by him/her under his/her personal supervision. To be covered, drugs and biologicals must be an

Erbitux® (Cetuximab)
expense to the physician billing for the service. For example, if a patient purchases a drug and the physician administers it, the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

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. The following guidelines identify three categories in which medications would not be reasonable and necessary according to accepted standards of medical practice:

- **Not for Particular Illness**: Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations).
- **Injection Method Not Indicated**: Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.
- **Excessive Medications**: Medications administered for treatment of a disease which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered.

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.

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).

A drug that is less than effective is not eligible for reimbursement, i.e., one that the Food and Drug Administration has determined to lack substantial evidence of effectiveness for all labeled indications. Any other drug product that is identical, similar, or related, will also be ineligible.

If a use is identified as not indicated by CMS or the FDA or if a use is specifically identified as not indicated (in one or more of the three compendia mentioned) or if it is determined (based on peer reviewed medical literature) that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered. In this instance, the administration is also not covered.

Several cancer chemotherapeutic agents and regimes have been developed and approved by the Food and Drug Administration (FDA) to treat various types of cancer. The intended mechanism of action is to interfere with or prevent the growth of malignant (cancerous) cells.

Generally, cancer chemotherapeutic agents are covered only if all of the following requirements are met:

- Documentation is present to support that the drug is safe and effective and is being administered for an approved indication.
- Documentation in the patient’s medical record supports the medical necessity of administering the chemotherapy drug to that individual patient.
- Documentation in the patient’s medical record supports that the chemotherapy drug was administered as billed.
Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals. 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 ratings listed below:

- National Comprehensive Cancer Network (NCCN) Drugs and Biologies 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. In general, a use is identified by a compendium as medically accepted if the:

- Indication is a Category 1 or 2A in NCCN
- Class I, Class IIa, or Class IIb in DrugDex;
- Narrative text in AHFS or Clinical Pharmacology is supportive; or
- Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "evidence level A"

If a use is identified as not indicated by CMS or the FDA or if a use is specifically identified as not indicated (in one or more of the compendia mentioned) or if it is determined (based on peer reviewed medical literature) that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered. In this instance, the administration is also not covered. Self-administered drugs are not covered and should not be submitted to Medicare unless requested to do so by the beneficiary. (See Self-Administered Drug(s) (SAD) Policy.)

The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. An invoice may be requested if pricing is not available on the ASP pricing file. This file contains lists for NOC and true codes. This file can be located using the following web link: [http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice](http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice).

Chemotherapy Administration

Chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for autoimmune conditions) or to substances such as Monoclonal antibody agents and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumab, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients are not considered chemotherapy administration. If performed to facilitate the chemotherapy infusion or injection, the following services and items are included and are not separately billable:

- Use of local anesthesia;
- IV access;
- Access to indwelling IV, subcutaneous catheter or port;
- Flush at conclusion of infusion;
- Standard tubing, syringes and supplies; and
- Preparation of chemotherapy agent(s).

Payment for the above is included in the payment for the chemotherapy administration service. If a significant separately identifiable evaluation and management service is performed, the appropriate E & M code should be reported utilizing modifier 25 in addition to the chemotherapy code. For an evaluation and management service provided on the same day, a different diagnosis is not required.

**Coding Guidelines**

- Use the appropriate J code to report the drug being used.
- True codes reflect the dosage of the drug; the number of units should indicate the total number of units given in 2400/SV1-04 data element of the ANSI 837 5010 or in item 24G of the CMS 1500 form.
**Documentation Requirements**
Medical record documentation maintained by the ordering/referring physician must substantiate the medical need for the use of these chemotherapy drugs by clearly indicating the condition for which these drugs are being used. This found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician’s order for the chemotherapy drug. The physician must state the clinical indication/medical need for using the chemotherapy drug in the order.

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);
- The duration of the administration (for CPT codes that are time based); and
- If a vascular access device/pump is used then the type of device must be documented along with the other information previously noted.

Refer to national policy: [Medicare Claims Processing Manual – Pub. 100-04, Chapter 17, Section 40](#).

**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.

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**ICD-10 Diagnosis Codes**

[Erbitux ICD-10 Dx Coding.xlsx](Erbitux ICD-10 Dx Coding.xlsx)

**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 Determinations (NCDs)**

[NC 110.7 Anti-Cancer Chemotherapy for Colorectal Cancer](NC 110.7 Anti-Cancer Chemotherapy for Colorectal Cancer)
### CMS Local Coverage Determinations (LCDs)

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### CMS Articles

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UnitedHealthcare Medicare Advantage Policy Guideline
Approved 09/14/2016

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**CMS Benefit Policy Manual**
*Chapter 15; § 50 Drugs and Biologicals*

**CMS Claims Processing Manual**
*Chapter 17; § 40 Discarded Drugs and Biologicals*

**CMS Transmittals**
*Transmittal 38, Change Request 3742, Dated 06/17/2005 (Coverage of Colorectal Anti-Cancer Drugs Included in Clinical Trials)*
*Transmittal 157, Change Request 7847, Dated 06/08/2012 (July 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS))*

**MLN Matters**
*Article MM3742, Anti-Cancer Chemotherapy for Colorectal Cancer*

**UnitedHealthcare Commercial Policies**
*Oncology Medication Clinical Coverage Policy*

**Others**
*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**
- **1833(e) Incomplete Claim**

**GUIDELINE HISTORY/REVISION INFORMATION**

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