Important Note About This Reimbursement Policy

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided.

UnitedHealthcare reimbursement policies 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.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents. Finally, UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Reimbursement Policy

Anti-Cancer Chemotherapy for Colorectal Cancer
(NCD 110.17)

Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

Summary

Overview
Oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), and bevacizumab (Avastin™) are anti-cancer chemotherapeutic agents approved by the Food and Drug Administration (FDA) for the treatment of colorectal cancer. Anti-cancer chemotherapeutic agents are eligible for coverage when used in accordance with Food and Drug Administration (FDA)-approved labeling (see section 1861(t)(2)(B) of the Social Security Act (the Act)), when the off-label use is supported in one of the authoritative drug compendia listed in section 1861(t)(2)(B)(ii)(I) of the Act, or when the Medicare contractor determines an off-label use is medically accepted based on guidance provided by the Secretary (section 1861(t)(2)(B)(ii)(II).

Reimbursement Guidelines
Pursuant to this national coverage determination, the off-label use of clinical items and services, including the use of the studied drugs oxaliplatin, irinotecan, cetuximab, or bevacizumab, are covered in specific clinical trials identified by the Centers for Medicare & Medicaid Services (CMS). The clinical trials identified by CMS for coverage of clinical items and services are sponsored by the National Cancer Institute (NCI) and study the use of one or more off-label uses of these four drugs in colorectal cancer and in other cancer types. The list of identified trials is on the CMS website.

Other
This policy does not alter Medicare coverage for items and services that may be covered or non-covered according to the existing national coverage policy for Routine Costs in a Clinical Trial (National Coverage Determination Manual, section 310.1). Routine costs will continue to be covered as well as other items and services provided as a result of coverage of these specific trials in this policy. The basic requirements for enrollment in a trial remain unchanged. The existing requirements for coverage of oxaliplatin, irinotecan, cetuximab, bevacizumab, or other anticancer chemotherapeutic agents for FDA-approved indications or for indications listed in an approved compendium are not modified.

Contractors shall continue to make reasonable and necessary coverage determinations under section 1861(t)(2)(B)(ii)(II) of the Act based on guidance provided by the Secretary for medically accepted uses of off-label indications of oxaliplatin, irinotecan, cetuximab, bevacizumab, or other anticancer chemotherapeutic agents provided outside of the identified clinical trials appearing on the CMS website noted above.

CPT/HCPCS Codes

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<tr>
<td>J9035</td>
<td>Injection, bevacizumab, 10 mg (Avastin)</td>
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## Anti-Cancer Chemotherapy for Colorectal Cancer (NCD 110.17)

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<td>J9206</td>
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<td>J9263</td>
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### References Included (but not limited to):

- **CMS NCD**
  - NCD 110.17 Anti-Cancer Chemotherapy for Colorectal Cancer
- **CMS LCD(s)**
  - Numerous LCDs
- **CMS Article(s)**
  - Numerous Articles
- **CMS Benefit Policy Manual**
  - Chapter 1; § 30 Drugs and Biologicals
  - Chapter 6; § 30 Drugs and Biologicals
  - Chapter 7; § 40.1.2.4 Administration of Medications, § 80 Specific Exclusions From Coverage as Home Health Services, § 80.1 Drugs and Biologicals
  - Chapter 15; § 50 Drugs and Biologicals
- **CMS Claims Processing Manual**
  - Chapter 1; § 30.2.2A Background and Purpose of Reassignment Rules - Claims Submitted to B/MACs (Who is Supplier of Services), § 30.3.12.3 Physician/Practitioner/Supplier Participation Agreement and Assignment - Carrier Claims (Carrier Rules for Limiting Charge), § 50.2.2 Frequency of Billing for Providers Submitting Institutional Claims With Outpatient Services
  - Chapter 4; § 230 Billing and Payment for Drugs and Drug Administration, § 230.1 Coding and Payment for Drugs and Biologicals and Radiopharmaceuticals, § 230.2 Coding and Payment for Drug Administration
  - Chapter 12; § 30.5D,E Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions
  - Chapter 17; Drugs and Biologicals
- **UnitedHealthcare Medicare Advantage Coverage Summaries**
  - Chemotherapy, and Associated Drugs and Treatments
- **UnitedHealthcare Reimbursement Policies**
  - Avastin (Bevacizumab)
  - Camptosar (Irinotecan)
  - Discarded Drugs and Biologicals
  - Eloxatin (Oxaliplatin)
  - Erbitux (Cetuximab)
  - Medically Unlikely Units
  - Self-Administered Drug(s)
- **UnitedHealthcare Medical Policies**
  - Oncology Medication Clinical Coverage Policy
- **Others**
  - NCCN Drugs & Biologics Compendium website

### History

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