
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 38

Date: JUNE 17, 2005

CHANGE REQUEST 3742

SUBJECT: Coverage of Colorectal Anti-Cancer Drugs Included in Clinical Trials

NOTE: Transmittal 30, dated March 29, 2005, is rescinded and replaced with Transmittal 38, dated June 17, 2005. The implementation date for FIs is changed from April 18, 2005, to on or before July 5, 2005. There is no change to the implementation date of April 18, 2005, for Carriers. All other information remains the same.

I. SUMMARY OF CHANGES: The Centers for Medicare & Medicaid Services will cover the use of oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbix™), or bevacizumab (Avastin™) in clinical trials identified by CMS and sponsored by the National Cancer Institute. The clinical trials for which the off-label use of these drugs are covered appear in Appendix A in the NCD Manual, section 110.17 on the following CMS Web site: <http://www.cms.hhs.gov/coverage/download/id90b.pdf>. This decision does not modify existing requirements for coverage of these and other anti-cancer chemotherapeutic agents for FDA-approved indications or for indications listed in an approved compendium. This decision also does not change existing coverage for any off-label uses of these drugs provided outside the clinical trials identified. Contractors shall continue to make local coverage determinations for medically accepted uses of off-label indications based on guidance provided by the Secretary.

(This addition of section 110.17, to Pub. 100-03, is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. The NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR §§405.732, 405.860). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 28, 2005

***IMPLEMENTATION DATE:**

April 18, 2005 for Carriers

On or before July 5, 2005 for Fiscal Intermediaries

II. CHANGES IN MANUAL INSTRUCTIONS:

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|-------|----------------------------------|
| R | 1/Table of Contents |

| | |
|----------|--|
| N | 1/110.17/Anti-cancer Chemotherapy for Colorectal Cancer (Effective January 28, 2005) |
|----------|--|

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

| | |
|----------|--------------------------------------|
| | Business Requirements |
| X | Manual Instruction |
| | Confidential Requirements |
| | One-Time Notification |
| | Recurring Update Notification |

***Medicare contractors only**

Unless otherwise specified, the effective date is the date of service.

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.25)

Coverage Determinations

Table of Contents

(Rev. 38, 06-17-05)

110.17 – Anti-cancer Chemotherapy for Colorectal Cancer (Effective January 28, 2005)

110.17 – Anticancer Chemotherapy for Colorectal Cancer (Effective January 28, 2005)

(Rev. 38, Issued: 06-17-05; Effective: 01-28-05; Implementation: April 18, 2005 for Carriers On or before July 5, 2005 for Fiscal Intermediaries)

A. General

Oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbix™), 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)).

B. Nationally Covered Indications

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 at: <http://www.cms.hhs.gov/coverage/download/id90b.pdf>.

C. 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.

(This NCD last reviewed March 2005.)