



MLN Matters®



Information for Medicare Fee-For-Service Health Care Professionals

Related Change Request (CR) #: 3742

MLN Matters Number: MM3742

Related CR Release Date: June 17, 2005

Related CR Transmittal #: 38 and 588

Effective Date: January 28, 2005

Implementation Date: April 18, 2005 for Medicare carriers

On or before July 5, 2005 for Medicare Fiscal Intermediaries

Note: This article was updated on February 4, 2013, to reflect current Web addresses. All other information remains unchanged.

Anti-Cancer Chemotherapy for Colorectal Cancer

Provider Types Affected

Providers and suppliers billing Medicare carriers, including Durable Medical Equipment Regional Carriers (DMERCs), and fiscal intermediaries (FIs) for anti-cancer chemotherapy

Provider Action Needed

This article is based on information contained in Change Request (CR) 3742, which states that the Centers for Medicare & Medicaid Services (CMS) will cover the off-label use of Oxaliplatin (Eloxatin™), Irinotecan (Camptosar®), Cetuximab (Erbix™), or Bevacizumab (Avastin™) in clinical trials identified by CMS and sponsored by the National Cancer Institute (NCI).

This national coverage decision does not:

- Modify existing requirements for coverage of these and other anti-cancer chemotherapeutic agents for FDA-approved indications or for off-label indications listed in an approved compendium; or
- Change existing coverage for any off-label uses of these drugs provided outside the clinical trials identified.

Medicare carriers, DMERCs, and intermediaries will continue to make local coverage determinations for medically accepted uses of off-label indications based on guidance provided by the Secretary of the Department of Health and Human Services (DHHS).

Background

On January 28, 2005, CMS announced a National Coverage Determination (NCD) covering the off-label use of certain colorectal anti-cancer drugs in identified clinical trials of colorectal cancer and other cancer

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types. These clinical trials study the use of one or more off-label uses of these four drugs in colorectal and other cancer types.

Note: The clinical trials for which these drugs and other items and services are covered appear in Appendix A in the NCD at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> on the CMS web site.

Anti-cancer chemotherapeutic agents are eligible for coverage in a clinical trial setting when the following occurs:

- They are used in accordance with Food and Drug Administration (FDA)-approved labeling;
- Their use is supported in one of the authoritative drug compendia; or
- The Medicare contractor (carriers, Fiscal Intermediaries (FIs), DMERCs) determines an off-label use is medically accepted based on guidance provided by Secretary of DHHS.

Effective for services provided on or after January 28, 2005, CMS covers the following anti-cancer chemotherapeutic agents, which have been approved by the FDA for the treatment of colorectal cancer, when used in clinical trials identified by CMS and sponsored by the National Cancer Institute:

- Oxaliplatin (Eloxatin™)
- Irinotecan (Camptosar®)
- Cetuximab (Erbix™)
- Bevacizumab (Avastin™)

Under the concept of linking Medicare coverage determinations to clinical studies, the investigational items and services provided in qualified scientific studies are covered (including clinical trials, practical trials, and systematic data collection systems) when:

- They provide for the accrual of supporting evidence of medical necessity; and
- They collect data to support decisions about whether or not a technology is reasonable and necessary.

Note: The list of identified clinical trials for which the routine costs of the items and services are covered appears in the Clinical Trials section, at <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html> on the CMS website.

Non-routine clinical costs include items and services that are provided in either the investigational or the control arms of a clinical trial specified by CMS for coverage. The following non-routine items and services **are not covered** and include items and services:

- Provided solely to satisfy data collection, and that are not used in the direct clinical management of the patient;
- Provided solely to determine trial eligibility;
- Customarily provided by the research sponsors free-of-charge for any enrollee in the trial;
- That are statutorily excluded from Medicare coverage; or

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- That do not fall into a benefit category.

This NCD, issued on January 28, 2005, does not withdraw Medicare coverage for items and services that may be covered according to the existing national coverage policy for Routine Costs in a Clinical Trial (See National Coverage Determination Manual, Section 310.1 at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html> on the CMS website.

Note: 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.

Medicare contractors will continue to make reasonable and necessary coverage determinations under the Social Security Act (Section 1861(t)(2)(B)(ii)(II)) based on guidance provided by CMS 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 previously.

Some important points to remember when billing Medicare for these anti-cancer drugs are as follows:

- FIs will accept claims for these drugs on types of bill (TOB) 11x, 12x, 13x, 18x, 21x, 22x, 23x, and 85x. Use revenue code 0636 used for anti-cancer drugs furnished during a clinical trial for outpatient claims and use revenue code 0250 for inpatient claims.
- When billing carriers, DMERCs and FIs, on a claim other than an inpatient claim, include the QR modifier to show the drug was furnished during a clinical trial.
- Claims submitted to FIs should also contain an ICD-9-CM diagnosis code of V70.7 in the second diagnosis code position to show that the claim involves a clinical trial.
- When using the QR modifier, also be sure to include a HCPCS code of J9035, J9055, J9206, J9263, J8520, J8521, J9190, or J9201, as appropriate for the anti-cancer drug being billed.
- Providers are also to include a QR modifier when billing for nonroutine costs associated with these clinical trials.
- DMERCs will accept claims with HCPCS codes of J8520 and J8521 as clinical trial codes for **oral anti-cancer** drugs, when accompanied by the QR modifier to show use in a clinical trial.
- When billing for covered routine costs associated with clinical trials as described in section 310 of the NCD Manual, be sure to include a QV modifier on the claim.
- Submit an appropriate cancer diagnosis code for the clinical trial on the claim.

Note: While this NCD is effective as of January 28, 2005, Medicare systems will be unable to process claims containing the QR modifier received before April 1, 2005. For that reason, do not send in claims for drugs or other nonroutine services covered under this NCD until April 1, 2005. Do not hold claims for nonroutine services containing the QV modifier associated with this NCD.

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Additional Information

For complete details, please see the official instruction issued to your carrier/DMERC/intermediary regarding this change. That instruction includes the NCD section 110.17 and it may be viewed by going to <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R38NCD.pdf> and <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R588CP.pdf> on the CMS website.

The version of CR3742 with a transmittal number of R38NCD will contain the NCD information and the version with a transmittal number of R588CP will contain the Medicare claims processing instructions.

If you have any questions, please contact your carrier/DMERC/intermediary at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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