



Related MLN Matters Article #: MM3742

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Anti-Cancer Chemotherapy for Colorectal Cancer

Key Words

Chemotherapy, Colorectal, Cancer, NCD, Oxaliplatin, Irinotecan, Cetuximab, Bevacizumab, Anti-cancer, Agents, Clinical, Trials, Non-routine, Drugs, MM3742, CR3742, R588CP, R38NCD, Investigational

Provider Types Affected

Providers and suppliers billing Medicare carriers, including durable medical equipment regional carriers (DMERCs) and fiscal intermediaries (FIs) for anti-cancer chemotherapy

Key Points

- The effective date of the instruction is January 28, 2005.
- The implementation dates are April 18, 2005, for Medicare carriers and on or before July 5, 2005, for Medicare fiscal intermediaries.
- The Centers for Medicare & Medicaid Services (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 types on January 28, 2005.
- 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™)
- This national coverage decision regarding these anti-cancer chemotherapeutic agents 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 contractors 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).
- 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 determines an off-label use is medically accepted based on guidance provided by Secretary of DHHS.
- Under the concept of linking Medicare coverage determinations to clinical studies, the investigational items and services provided in qualified scientific studies are covered 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.
- 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;
 - Are statutorily excluded from Medicare coverage; or
 - Do not fall into a benefit category.

Important Links

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3742.pdf>

<http://www.cms.hhs.gov/Transmittals/downloads/R588CP.pdf>

<http://www.cms.hhs.gov/Transmittals/downloads/R38NCD.pdf>