CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 588 **Date: JUNE 17, 2005**

CHANGE REQUEST 3742

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

NOTE: Transmittal 567, dated May 20, 2005, is rescinded and replaced with Transmittal 588, dated June 17, 2005.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 (CMS) will cover the off-label use of oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), or bevacizumab (Avastin™) in certain specific 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 off-label indications listed in an approved compendium. This decision also does not alter 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.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 28, 2005
IMPLEMENTATION DATE:
April 18, 2005 for Carriers
On or before July 5, 2005 for Fiscal Intermediaries

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

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

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 588	Date: June 17, 2005	Change Request 3742

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

I. GENERAL INFORMATION

A. Background: On January 28, 2005, 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 specific clinical trials of colorectal cancer and other cancer types.

B. Policy: CMS will cover the off-label use of oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), or bevacizumab (Avastin™) in 9 clinical trials identified by CMS and sponsored by the National Cancer Institute. These clinical trials study the use of 1 or more off-label uses of these 4 drugs in colorectal and other cancer types. 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.

Coverage is also provided for costs of other items and services provided in either the experimental or control arms of the specified clinical trials under the existing national coverage policy for "routine" costs in a clinical trial (NCD Manual, section 310.1). Providers are to use the newly created QR modifier to identify "non-routine" costs of these 9 trials, including the administration costs of the items/services/drugs provided in the clinical trials that are not generally covered.

This decision makes no change in coverage for any off-label uses of these drugs provided outside of the clinical trials identified in section 110.17 of the NCD Manual. Contractor discretion continues in making local determinations of reasonable and necessary for medically accepted uses of off-label indications based on existing guidance provided by the Secretary. This decision does not modify the existing requirement for coverage of these and other anticancer chemotherapeutic agents for FDA-approved indications or for off-label indications listed in an approved compendium.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)					
		FI	RHH	Car	DME	Shared System Maintainers	Oth

						FISS	MCS	VMS	CWF	
3742.1	Effective January 28, 2005, FIs shall pay claims with the following TOBs for anti-cancer drugs furnished during a clinical trial as defined in 3742.2.1: • 11x • 12x • 13x • 18x • 21x • 22x • 23x • 85x	X								
3742.2	Contractors shall recognize modifier QR as the appropriate modifier for reporting anti-cancer drugs furnished during a clinical trial, as defined in section 110.17 of the NCD Manual, on claims other than inpatient claims.	X		X	X	X	X			
3742.2.1	FIs shall advise providers to enter ICD-9-CM diagnosis code V70.7 in the second diagnosis code position. This code alerts the claim processing system that this is a clinical trial.	X				X				
3742.2.2	FIs shall return to providers any claims not containing both the QR modifier and the V70.7 diagnosis code as defined in 3742.2.1.	X								
3742.3	Carriers and FIs shall pay for the following anti-cancer drugs according to the NCD described above when these drugs are covered and a QR modifier appears on the claim: J9035 J9055 J9206 J9263 J8520 J8521 J9201 J9190	X		X		X	X			
3742.4	FIs shall pay inpatient claims for the anti-cancer drugs described in 3742.3 according to the NCD when these drugs are covered and diagnosis code V70.7 is entered in the second code position.	X				X				

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3742.5	FIs shall pay claims with revenue code 0636 (drugs requiring detailed coding) for anti-cancer drugs furnished during a clinical trial for outpatient claims and revenue code 0250 for inpatient claims.	X								
3742.6	Contractors shall apply appropriate payment methodologies, rates and payment policies regarding drugs in general, including appropriately applying policies related to the administration of drugs and incident to services.	X		X	X		X	X		
3742.7	DMERCs and VMS shall recognize HCPCS codes J8520 and J8521 as clinical trial codes for **oral** anti-cancer drugs when the QR modifier is attached.				X			X		
3742.8	Contractors shall pay for covered routine costs associated with the clinical trials described in the NCD, section 310 and including the QV modifier.	X		X	X		X	X		
3742.9	Contractors shall pay for covered non-routine costs associated with the clinical trials described in the NCD, section 310 and including the QR modifier.	X		X	X	X	X	X		
3742.10	Contractors shall recognize any appropriate cancer diagnosis code for this trial.	X		X	X		X	X		
3742.11	Contractors shall hold claims received April 1, 2005, and later, and begin to process claims no later than April 18, 2005. The installation of the April outpatient code editor (OCE), version 6.1, is effective April 4, 2005.	X		X	X					OCE
3742.12	FIs shall identify all held claims with condition code 15, upon release.	X								
3742.13	DMERCs shall map to the NDC crosswalk, select corresponding HCPCS code, and pay on basis of the appropriate HCPCS code. The NDC crosswalk is located at: http://www.cms.hhs.gov/providers/drugs/asp.asp				X			X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3742.14	Carriers and DMERCs shall use Type of Service (TOS) 1,P for all the codes (J8520-J8521-J9035-J9055-J9190-J9201-J9206-J9263).			X	X		X	X		

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3742.15	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "Medlearn Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X					

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting / Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 28, 2005 **Implementation Date:** ***April 18, 2005 for Carriers*** ***On or before July 5, 2005 for Fiscal Intermediaries*** **Pre-Implementation Contact(s):** Claudette Sikora (Part B claims), 410-786-5618, Bill Ruiz (Part A claims), 410-786-9283, Michael Lyman (coverage), 410-786-6938, Pat Brocato-Simons (coverage), 410-786-0261, Tracey Hemphill, Wendy Knarr (DMERCs), 410-786-7169 **Post-Implementation Contact(s):** Appropriate RO	**Medicare contractors shall implement these instructions within their current operating budgets.**

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