

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 105</b>	<b>Date: August 7, 2009</b>
	<b>Change Request 6578</b>

**SUBJECT: Screening Computed Tomography Colonography (CTC) for Colorectal Cancer**

**I. SUMMARY OF CHANGES:** CMS determines that the current evidence is inadequate to conclude that CTC is an appropriate colorectal cancer screening test under section 1861(pp)(1) of the Social Security Act. Therefore, effective May 12, 2009, CTC for colorectal cancer screening remains nationally non-covered.

**NEW / REVISED MATERIAL**

**EFFECTIVE DATE: \*MAY 12, 2009**

**IMPLEMENTATION DATE: September 8, 2009**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. 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: (N/A if manual is not updated)**

**R=REVISED, N=NEW, D=DELETED**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	1/210.3/Colorectal Cancer Screening Tests

**III. FUNDING:**

**SECTION A: For Fiscal Intermediaries and Carriers:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**SECTION B: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

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

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 105	Date: August 7, 2009	Change Request: 6578
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**SUBJECT: Screening Computed Tomography Colonography (CTC) for Colorectal Cancer**

**Effective Date: May 12, 2009**

**Implementation Date: September 8, 2009**

## I. GENERAL INFORMATION

**A. Background:** The Centers for Medicare & Medicaid Services (CMS) covers colorectal cancer screening for average risk individuals age 50 and older using fecal occult blood testing, sigmoidoscopy, colonoscopy, and barium enema. On March 5, 2008, the American Cancer Society, the US Multi Society Task Force on Colorectal Cancer, and the American College of Radiology issued new cancer screening guidelines, including a recommendation that CTC be considered an acceptable option for colorectal cancer screening for such individuals. CTC, also referred to as virtual colonoscopy, uses computed tomography (CT) to acquire images and advanced 2-dimensional (2D) or 3-dimensional (3D) image display techniques for interpretation. Neither the Medicare law nor the regulations identify the CTC test as a possible coverage option under the colorectal cancer screening benefit. However, under 42 CFR 410.37(a)(1), CMS is allowed to use the NCD process to determine coverage of other types of colorectal cancer screening tests that are not specifically identified in the law or regulations as it determines to be appropriate, in consultation with appropriate organizations.

**B. Policy:** On May 19, 2008, CMS internally generated a review of the use of screening CTC for colorectal cancer to determine whether the scope of the existing CRC screening benefit should be expanded to include coverage of the CTC screening test. Following a thorough review of the evidence, meetings with medical professional organizations, and conducting a Medicare Evidence Development and Coverage Advisory Committee Meeting, CMS determines that the current evidence is inadequate to conclude that CTC is an appropriate colorectal cancer screening test under section 1861(pp)(1) of the Social Security Act. Therefore, effective May 12, 2009, CTC for colorectal cancer screening remains nationally non-covered.

## II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement*

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
6578.1	Effective for claims with dates of service on and after May 12, 2009, contractors shall continue to process CTC for colorectal cancer screening as nationally non-covered by Medicare. No changes to claims processing and systems edits are necessary.	X		X	X					

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6578.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles">http://www.cms.hhs.gov/MLNMattersArticles</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN 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

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below:**

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: For all other recommendations and supporting information, use this space:**

### V. CONTACTS

**Pre-Implementation Contact(s):** William Larson, coverage, 410-786-4639. [william.larson@cms.hhs.gov](mailto:william.larson@cms.hhs.gov), Michelle Atkinson, coverage, 410-786-2881, [michelle.atkinson@cms.hhs.gov](mailto:michelle.atkinson@cms.hhs.gov), Pat Brocato-Simons, coverage, 410-786-0261, [patricia.brocato-simons@cms.hhs.gov](mailto:patricia.brocato-simons@cms.hhs.gov).

**Post-Implementation Contact(s):** Regional offices

### VI. FUNDING

**Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B: *For Medicare Administrative Contractors (MACs):***

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

## **210.3 – Colorectal Cancer Screening Tests**

*(Rev. 105, Issued: 08-07-09, Effective: 05-12-09, Implementation: 09-08-09)*

### **A. General**

Section 4104 of the Balanced Budget Act of 1997 provides for coverage of screening colorectal cancer procedures under Medicare Part B. Medicare currently covers: (1) annual fecal occult blood tests (FOBTs); (2) flexible sigmoidoscopy over 4 years; (3) screening colonoscopy for persons at average risk for colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years; (4) barium enema every 4 years as an alternative to flexible sigmoidoscopy, or every 2 years as an alternative to colonoscopy for persons at high risk for colorectal cancer; and, (5) other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.

Coverage of the above screening examinations was implemented in regulations through a final rule that was published on October 31, 1997 (62 FR 59079), and was effective January 1, 1998. At that time, based on consultation with appropriate experts and organizations, the definition of the term “FOBT” was defined in 42 CFR §410.37(a)(2) of the regulation to mean a “guaiac-based test for peroxidase activity, testing two samples from each of three consecutive stools.” In the 2003 Physician Fee Schedule Final Rule (67 FR 79966) effective March 1, 2003, the Centers for Medicare & Medicaid Services (CMS) amended the FOBT screening test regulation definition to provide that it could include either: (1) a guaiac-based FOBT, or, (2) other tests determined by the Secretary through a national coverage determination.

### **B. Nationally Covered Indications**

Fecal Occult Blood Tests (FOBT) (effective for services performed on or after January 1, 2004)

#### **1. History**

The FOBTs are generally divided into two types: immunoassay and guaiac types. Immunoassay (or immunochemical) fecal occult blood tests (iFOBT) use “antibodies directed against human globin epitopes. While most iFOBTs use spatulas to collect stool samples, some use a brush to collect toilet water surrounding the stool. Most iFOBTs require laboratory processing. Guaiac fecal occult blood tests (gFOBT) use a peroxidase reaction to indicate presence of the heme portion of hemoglobin. Guaiac turns blue after oxidation by oxidants or peroxidases in the presence of an oxygen donor such as hydrogen peroxide. Most FOBTs use sticks to collect stool samples and may be developed in a physician’s office or a laboratory. In 1998, Medicare began reimbursement for guaiac FOBTs, but not immunoassay type tests for colorectal cancer screening. Since the fundamental process is similar for other iFOBTs, CMS evaluated colorectal cancer screening using immunoassay FOBTs in general.

#### **2. Expanded Coverage**

Medicare covers one screening FOBT per annum for the early detection of colorectal cancer. This means that Medicare will cover one guaiac-based (gFOBT) or one immunoassay-based (iFOBT) at a frequency of every 12 months; i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed, for beneficiaries aged 50 years and older. The beneficiary completes the existing gFOBT by taking samples from two different sites of three consecutive stools; the beneficiary completes the iFOBT by taking the appropriate number of stool samples according to the specific manufacturer's instructions. This screening requires a written order from the beneficiary's attending physician. ("Attending physician means a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Social Security Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.)

### **C. Nationally Non-Covered Indications**

All other indications for colorectal cancer screening not otherwise specified above remain non-covered. *Non-coverage specifically includes:*

- (1) Screening DNA (Deoxyribonucleic acid) stool tests, effective April 28, 2008, and,*
- (2) Screening computed tomographic colonography (CTC), effective May 12, 2009.*

### **D. Other**

N/A

**(This NCD last reviewed *May 2009*.)**