CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 92	**Date: August 8, 2008**
	Change Request 6145

NOTE: Transmittal 89, dated July 25, 2008, is rescinded and replaced by Transmittal 92, dated August 8, 2008. The Implementation Date on the Business Requirements was erroneously stated as August 25, 2005. The correct Implementation Date is August 25, 2008. All other material remains the same.

SUBJECT: Screening DNA Stool Test for Colorectal Cancer

I. SUMMARY OF CHANGES: Following reconsideration of the current national coverage determination (NCD) for colorectal cancer screening, CMS proposes not to expand the colorectal cancer screening benefit to include coverage of PreGen-Plus, a commercially available screening DNA stool test. The FDA determines that this test requires premarket review and approval. A subsequent request for reconsideration will be considered once FDA approval is obtained.

This revision of Pub.100-03, section 210.3 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare Advantage Organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

New / Revised Material
Effective Date: April 28, 2008
Implementation Date: August 25, 2008

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	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: 92	Date: August 8, 2008	Change Request: 6145

NOTE: Transmittal 89, dated July 25, 2008, is rescinded and replaced by Transmittal 92, dated August 8, 2008. The Implementation Date on the Business Requirements was erroneously stated as August 25, 2005. The correct Implementation Date is August 25, 2008. All other material remains the same.

SUBJECT: Screening DNA Stool Test for Colorectal Cancer

Effective Date: April 28, 2008

Implementation Date: August 25, 2008

I. GENERAL INFORMATION

A. Background: Congress has specifically authorized coverage of certain screening tests under Part B of the Medicare program and has made necessary conforming changes in order to ensure that payments are made. As a result, the Centers for Medicare & Medicaid Services (CMS) currently covers colorectal cancer screening for average-risk individuals ages 50 years and older using fecal occult blood testing, sigmoidoscopy, colonoscopy, and barium enema. Neither the law nor regulations identify screening DNA stool tests as a possible coverage option under the colorectal cancer screening benefit. However, under 42 CFR 410.37(a)(1)(v), and section 1861(pp)(1)(D) of the Social Security Act, CMS is allowed to use the national coverage determination (NCD) process to determine coverage of other types of colorectal cancer screening tests not specifically identified in the law or regulations as it determines to be appropriate, and in consultation with appropriate organizations.

B. Policy: Following an external request for reconsideration of the current NCD at Pub. 100-03, National Coverage Determinations Manual, section 210.3, CMS proposes not to expand the colorectal cancer screening benefit to include coverage of PreGen-Plus™, a commercially available screening DNA stool test, as an alternative to a screening colonoscopy or a screening flexible sigmoidoscopy. The Food and Drug Administration (FDA) determines that this test is a medical device that requires pre-market review and approval prior to marketing, which, to date, has not been obtained. In the absence of an FDA determination, CMS believes that there may be unresolved questions regarding the safety and effectiveness of the stool DNA test, and therefore does not believe that identification of stool DNA mutations is an appropriate colorectal cancer screening test at this time. A subsequent request for reconsideration will be considered once FDA approval is obtained.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6145.1	Contractors shall be aware that effective with a CMS final determination effective April 28, 2008, the NCD for Colorectal Cancer Screening Tests at Pub. 100-03,	X	X	X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	National Coverage Determinations Manual, section 210.3, remains unchanged. In addition, all current claims processing and billing requirements remain in effect (see Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 280 and Pub. 100-04, Medicare Claims Processing Manual, chapter 18, section 60).										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6145.2	Contractors shall post this entire instruction, or a direct link to this instruction, on their Web site and include information about it in a listserv message within 1 week of the release of this instruction. In addition, the entire instruction must be included in your next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	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:
	N/A

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

V. CONTACTS

Pre-Implementation Contact(s): Bill Larson, coverage, 410-786-4639, William.larson@cms.hhs.gov, Pat Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov

Post-Implementation Contact(s): Appropriate CMS RO

VI. FUNDING

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

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. 92; Issued: 08-08-08; Effective Date: 04-28-08; Implementation Date: 08-25-08)

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 at 42 CFR §410.37(a)(2) 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.

D. Other

N/A

(This NCD last reviewed April 2008.)