

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 93	Date: JULY 25, 2008
	Change Request 6145

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.

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	15/280/Preventive and Screening Services

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. 100-02	Transmittal: 93	Date: July 25, 2008	Change Request: 6145
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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, 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, 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 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	
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, 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).	X	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	
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.

280 – Preventive and Screening Services

(Rev. 93; Issued: 07-25-08; Effective Date: 04-28-08; Implementation Date: 08-25-08)

See section 50.4.4.2 for coverage requirements for PPV, hepatitis B vaccine, and Influenza Virus Vaccine.

See *Pub. 100-04*, Medicare Claims Processing Manual, Chapter 18, “Preventive and Screening Services,” for coverage requirements for the following:

- §40 for screening pelvic examinations,
- §50 for prostate cancer screening test and procedures,
- *§60 for colorectal cancer screening, and,*
- §70.4 for glaucoma screening.