CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 183	**Date: August 6, 2015**
	Change Request 9115

NOTE: This Transmittal is no longer sensitive and is being re-communicated August 28, 2015. Pub. 100-03 NCD Manual, Section 210.3, Colorectal Cancer Screening, has been revised to include minor formatting and editorial changes that do not impact on the policy criteria contained therein. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is effective for claims with dates of service on or after October 9, 2014, contractors shall recognize new HCPCS code G0464 (colorectal cancer screening; stool-based DNA and fecal occult hemoglobin) as a covered service.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, 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.)

EFFECTIVE DATE: October 9, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: September 8, 2015- For non-shared MAC edits; January 4, 2016 - For all shared system changes.

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-*Only One Per Row.*

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

III. FUNDING:
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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 183	Date: August 6, 2015	Change Request: 9115

NOTE: This Transmittal is no longer sensitive and is being re-communicated August 28, 2015. Pub. 100-03 NCD Manual, Section 210.3, Colorectal Cancer Screening, has been revised to include minor formatting and editorial changes that do not impact on the policy criteria contained therein. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test

EFFECTIVE DATE: October 9, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: September 8, 2015- For non-shared MAC edits; January 4, 2016 - For all shared system changes.

I. GENERAL INFORMATION

A. Background: Sections 1861(s)(2)(R) and 1861(pp) of the Social Security Act and regulations at 42 CFR 410.37 authorize Medicare coverage for colorectal cancer (CRC) screening tests under Medicare Part B. The statute and regulations authorize the Secretary to add other tests and procedures (and modifications to such tests and procedures for colorectal cancer screening) as the Secretary determines appropriate in consultation with appropriate organizations. As part of the Centers for Medicare & Medicaid Services (CMS) – Food and Drug Administration (FDA) Parallel Review Pilot Program, CMS finalized an NCD for Screening for CRC Using Cologuard™ - A Multitarget Stool DNA Test.

B. Policy: After considering public comments and consulting with appropriate organizations, effective October 9, 2014, CMS determined that the evidence is sufficient to cover Cologuard™ - a multitarget stool DNA test – as a colorectal cancer screening test for asymptomatic, average risk beneficiaries, aged 50 to 85 years.

Therefore, Medicare Part B will cover the Cologuard™ test once every three years for beneficiaries who meet all of the following criteria:

- Age 50 to 85 years,

- Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test), and

- At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, orhereditary nonpolyposis colorectal cancer).

All other screening stool DNA tests not otherwise specified above remain nationally non-covered.

NOTE: Only laboratories that are authorized by the manufacturer to perform the Cologuard™ test may bill for this test.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9115 - 03.1	Contractors shall be aware that effective for dates of service on and after October 9, 2014, contractors shall pay claims for colorectal cancer screening using Cologuard™ - a multitarget stool DNA test under Medicare Part B as described in Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, section 210.3, and Pub. 100-04, Medicare Claims Processing Manual, Chapter 18, Section 60.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9115 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ 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 sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's 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			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wendy Knarr, 410-786-0843 or Wendy.Knarr@cms.hhs.gov (Supplier Claims Processing) , Jamie Hermansen, 410-786-2064 or Jamie.Hermansen@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patti Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage) , Thomas Dorsey, 410-786-7434 or thomas.dorsey@cms.hhs.gov (Practitioner Claims Processing Part B) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Part A Institutional Claims Processing)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

210.3 – Colorectal Cancer Screening Tests
(Rev.183, Issued: 08-06-15; Effective: 10-09-14, Implementation: 09-08-2015- For non-shared MAC edits; 01-04-16 - For all shared system changes.)

A. General

Sections 1861(s)(2)(R) and 1861(pp) of the Social Security Act (the Act) and regulations at 42 CFR 410.37 authorize Medicare coverage for screening colorectal cancer tests under Medicare Part B. The statute and regulations authorize the Secretary to add other tests and procedures (and modifications to tests and procedures for colorectal cancer screening) as the Secretary finds appropriate based on consultation with appropriate experts and organizations.

B. Nationally Covered Indications

1. Fecal Occult Blood Tests (FOBT) (effective January 1, 2004)

Fecal occult blood tests (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*, the Centers for Medicare & Medicaid Services* evaluated colorectal cancer screening using immunoassay FOBTs in general.

Effective for dates of service on and after January 1, 2004, 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 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.)

2. The Cologuard™ - Multitarget Stool DNA (sDNA) Test (effective October 9, 2014)

Screening stool or fecal DNA (deoxyribonucleic acid, sDNA) testing detects molecular markers of altered DNA that are contained in the cells shed by colorectal cancer and pre-malignant colorectal epithelial

neoplasia into the lumen of the large bowel. Through the use of selective enrichment and amplification techniques, sDNA tests are designed to detect very small amounts of DNA markers to identify colorectal cancer or pre-malignant colorectal neoplasia. The Cologuard™ - multitarget sDNA test is a proprietary in vitro diagnostic device that incorporates both sDNA and fecal immunochemical test techniques and is designed to analyze patients' stool samples for markers associated with the presence of colorectal cancer and pre-malignant colorectal neoplasia.

Effective for dates of service on or after October 9, 2014, The Cologuard™ test is covered once every three years for Medicare beneficiaries that meet all of the following criteria:

- *Age 50 to 85 years, and,*
- *Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test (gFOBT) or fecal immunochemical test (iFOBT)), and,*
- *At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).*

C. Nationally Non-Covered Indications

All other indications for colorectal cancer screening not otherwise specified in the Act and regulations, or otherwise specified above remain nationally non-covered. Non-coverage specifically includes:

(1) All screening sDNA tests, effective April 28, 2008, through October 8, 2014. Effective for dates of service on or after October 9, 2014, all other screening sDNA tests not otherwise specified above remain nationally non-covered.

(2) Screening computed tomographic colonography (CTC), effective May 12, 2009.

D. Other

N/A

(This NCD last reviewed October 2014.)