CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 176	**Date: October 17, 2014**
	Change Request 8881

SUBJECT: Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) and Screening Fecal-Occult Blood Tests (FOBT)

I. SUMMARY OF CHANGES: Effective for dates of service on and after January 27, 2014, contractors shall pay claims for Ultrasound screening for AAA and screening FOBTs, per the modified requirements in 42 CFR 410.19 and 410.37.

EFFECTIVE DATE: January 27, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: November 18, 2014

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:
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 obliged 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: 176	Date: October 17, 2014	Change Request: 8881

SUBJECT: Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms (AAA) and Screening Fecal-Occult Blood Tests (FOBT)

EFFECTIVE DATE: January 27, 2014
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I. GENERAL INFORMATION

A. Background: Medicare Part B coverage of screening FOBTs is covered for certain beneficiaries that meet eligibility requirements, including that the beneficiary receives a written order for a screening FOBT from his/her attending physician. As part of the CY 2014 Physician Fee Schedule rule, CMS revised 42 CFR 410.37(b), the Medicare Part B coverage requirements for Screening FOBT, to allow the beneficiary's attending physician assistant, nurse practitioner, or clinical nurse specialist to furnish written orders for screening FOBT.

B. Policy: Effective for dates of service on and after January 27, 2014, a screening FOBT is covered if a written order is furnished by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist, and meets other coverage criteria outlined in 42 CFR 410.37.

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	
8881 - 03.1	Effective for dates of service on and after January 27, 2014, contractors shall pay claims for screening FOBT, if a written order for such test is furnished by the beneficiary's attending physician, physician assistant, or clinical nurse specialist, and meets other coverage criteria (See Pub. 100-03, chapter 1, section 210.3).	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8881 - 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 one week of the availability of the provider education 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): Jamie Hermansen, 410-786-2064 or Jamie.Hermansen@cms.hhs.gov (Coverage), Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage)

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

210.3 – Colorectal Cancer Screening Tests

(Rev. 176, Issued: 10-17-14, Effective: 01-27-14, Implementation: 11-18-14)

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*, or for claims with dates of service on or after January 27, 2014, by a beneficiary's attending physician assistant, nurse practitioner, or clinical nurse*

specialist. ("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