CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-03 Medicare National Coverage Determinations	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13921	**Date: August 27, 2026**
	Change Request 14581

SUBJECT: NCD 210.3 Screening for Colorectal Cancer-Non-Invasive Biomarker Tests

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that CMS has determined that effective June 8, 2026, non-invasive biomarker screening tests are appropriate colorectal cancer screening tests based on specific criteria.

EFFECTIVE DATE: June 8, 2026
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2027

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/Screening for Colorectal Cancer-Non-Invasive Biomarker 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: 13921	Date: August 27, 2026	Change Request: 14581

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EFFECTIVE DATE: June 8, 2026
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IMPLEMENTATION DATE: January 4, 2027

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that CMS has determined that effective June 8, 2026, non-invasive biomarker screening tests are appropriate colorectal cancer screening tests based on specific criteria.

II. 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.

B. Policy: Non-invasivebiomarker colorectal cancer screening testing detects molecular markers shed by colorectal cancer and pre- malignant colorectal epithelial neoplasia into blood, bodily secretions, or directly into the intestinal lumen. Through the use of selective enrichment and amplification techniques, tests are designed to detect very small amounts of markers to identify colorectal cancer or pre-malignant colorectal neoplasia.

Non-Invasive Biomarker tests are covered once every three years under the following conditions.

A. Ordering Criteria

1. When ordered by the physician, physician assistant, nurse practitioner, or clinical nurse specialist who will use the results in the management of the patient.

B. Patient Criteria

1. Age 45 to 85 years; and,
2. Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive non-invasive biomarker colorectal cancer screening test); and,
3. 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); and,
4. Provided with information about the test performance and the importance of a follow-on colonoscopy if the test returns a positive result.

C. Test Criteria

1. The test must be Food and Drug Administration (FDA) market authorized and indicated for colorectal cancer screening; and,

2. The test must achieve the requirements of the FDA-required post-approval study as specified in the Safety and Effectiveness Data (SSED) **to continue coverage**; and
3. The test must be processed in a Clinical Laboratory Improvement Amendment (CLIA) certified laboratory; and,
4. The test must demonstrate performance characteristics that meet **EITHER Criteria1,** a sensitivity of greater than or equal to 90% and a specificity greater than or equal to 87%, **OR Criteria 2,** a sensitivity of greater than or equal to 79% and a specificity of greater than or equal to 90% in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), based on the FDA labeling.

	Test Performance Criteria 1	**Test Performance Criteria 2**
Sensitivity for CRC	≥ 90%	≥ 79%
Specificity for CRC	≥ 87%	≥ 90%

III. BUSINESS REQUIREMENTS TABLE

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

Number	**Requirement**	**Responsibility**								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
14581 - 03.1	Effective June 8, 2026, contractors shall be aware that non-invasive biomarker tests for colorectal cancer screening are covered according to the provisions outlined in sections I.B. and I.C. of the Pub. 100-03 NCD Manual, chapter 1 section 210.3, and refer to Pub. 100-04 chapter 18, section 60 for claims processing instructions.	X	X							

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B

V. 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

VI. CONTACTS

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

VII. 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.13921; Issued: 08-27-26; Effective: 06-08-26; Implementation: 01-04-27)

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 organizations.

B. Nationally Covered Indications

1. Fecal Occult Blood Tests (FOBT)

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 gFOBTs, 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.

Medicare covers one screening FOBT per annum for the early detection of colorectal cancer. This means that Medicare will cover one gFOBT or one 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 45 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), physician assistant, nurse practitioner, or clinical nurse specialist* 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.)

The minimum age for FOBT is reduced to 45 years and older.

2. Non-Invasive Biomarker Tests

Biomarker testing detects molecular markers shed by colorectal cancer and pre- malignant colorectal epithelial neoplasia into blood, bodily secretions, or directly into the intestinal lumen. Through the use of selective enrichment and amplification techniques, tests are designed to detect very small amounts of markers to identify colorectal cancer or pre-malignant colorectal neoplasia.

Non-Invasive Biomarker tests are covered once every 3 years under the following conditions:

A. Ordering Criteria

1. *When ordered by the physician, physician assistant, nurse practitioner, or clinical nurse specialist who will use the results in the management of the patient.*

B. *Patient Criteria*

1. *Age 45 to 85 years; and,*
2. *Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive non-invasive biomarker colorectal cancer screening test); and,*
3. *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); and,*
4. *Provided with information about the test performance and the importance of a follow-on colonoscopy if the test returns a positive result.*

C. *Test Criteria*

1. *The test must be Food and Drug Administration (FDA) market authorized and indicated for colorectal cancer screening; and,*
2. *The test must achieve the requirements of the FDA-required post-approval study as specified in the Safety and Effectiveness Data (SSED) **to continue coverage**; and*
3. *The test must be processed in a CLIA certified laboratory; and,*
4. *The test must demonstrate performance characteristics that meet **EITHER Criteria 1,** a sensitivity of greater than or equal to 90% and a specificity greater than or equal to 87%, **OR Criteria 2,** a sensitivity of greater than or equal to 79% and a specificity of greater than or equal to 90% in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), based on the FDA labeling.*

	Test Performance Criteria 1	***Test Performance Criteria 2***
Sensitivity for CRC	*≥ 90%*	*≥ 79%*
Specificity for CRC	*≥ 87%*	*≥ 90%*

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.

D. Other

N/A

(This NCD was last reviewed June 2026 and includes updates finalized in the Calendar Year 2025 Physician Fee Schedule final rule 89 FR 97710)