

[Skip to Main Content](#)**Centers for Medicare & Medicaid Services**[Back to National Coverage Determinations \(NCDs\) Alphabetical Index](#)**National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3)****- Tracking Information**

<b>Publication Number</b> 100-3	<b>Manual Section Number</b> 210.3	<b>Manual Section Title</b> Colorectal Cancer Screening Tests
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<b>Version Number</b> 5	<b>Effective Date of this Version</b> 10/9/2014	<b>Implementation Date</b> 9/8/2015
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**Implementation QR Modifier Date**  
1/1/1900

**- Description Information**

**Benefit Category**  
Colorectal Cancer Screening Tests

**Note:** This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

**Item/Service Description****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.

**Indications and Limitations of Coverage****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.)

#### Cross Reference

Also see NCD for Fecal Occult Blood Test (§190.34).

#### Claims Processing Instructions

- TN 3319 (Medicare Claims Processing)
- TN 3436 (Medicare Claims Processing)

### - Transmittal Information

#### Transmittal Number

183

#### Coverage Transmittal Link

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R183NCD.pdf>

#### Revision History

12/2003 - Expanded Medicare coverage for screening for early detection of colorectal cancer by adding additional fecal occult blood test (iFOBT, immunoassay-based) that can be used as alternative to existing gFOBT, guaiac-based test. Medicare coverage continues to allow one FOBT per year for beneficiaries aged 50 and over. Effective date 1/01/04. Implementation date 1/05/2004 for coverage & HCPCS codes and 4/05/2004 for frequency edits. (TN 5) (CR 2996)

08/2008 - 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. Effective date 04/28/2008. Implementation date 08/25/2008. (TN 92) (CR6145)

08/2009 - CMS determines that the current evidence is inadequate to conclude that CTC is an appropriate colorectal cancer screening test under section 1861(pp)(1) of the Social Security Act. Therefore, effective May 12, 2009, CTC for colorectal cancer screening remains nationally non-covered. Effective date 05/12/2009. Implementation date 09/08/2009. (TN 105) (CR6578)

01/2013 - CMS translated the information for this policy from ICD-9-CM/PCS to ICD-10-CM/PCS according to HIPAA standard medical data code set requirements and updated any necessary and related coding infrastructure. These updates do not expand, restrict, or alter existing coverage policy. Implementation date: 04/01/2013 Effective date: 10/1/2015. (TN 1165) (CR 8109)

05/2014 - CMS translated the information for this policy from ICD-9-CM/PCS to ICD-10-CM/PCS according to HIPAA standard medical data code set requirements and updated any necessary and related coding infrastructure. These updates do not expand, restrict, or alter existing coverage policy. Implementation date: 10/06/2014 Effective date: 10/1/2015. (TN 1388) (TN 1388) (CR 8691)

10/2014 - Effective for dates of services 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 410.9 and 410.37. Effective date: 01/27/2014. Implementation date: 11/18/2014. (TN 176) (CR8881)

08/2015 - 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. Effective date: 10/09/2014 Implementation date: 09/08/2015. (TN 183) (CR9115)

08/2015 - This change request (CR) is the 3rd maintenance update of ICD-10 conversions/updates specific to national coverage determinations (NCDs). The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CR7818, CR8109, CR8197, CR8691, & CR9087. Some are the result of revisions required to other NCD-related CRs released separately that included ICD-10 coding. These updates do not expand, restrict, or alter existing coverage policy. Implementation date: 01/04/2016 Effective date: 10/1/2015. (TN 1537) (CR 9252)

12/2015 - This change request (CR) is the 3rd maintenance update of ICD-10 conversions/updates specific to national coverage determinations (NCDs). The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CR7818, CR8109, CR8197, CR8691, & CR9087. Some are the result of revisions required to other NCD-related CRs released separately that included ICD-10 coding. Implementation date: 01/04/2016 Effective date: 10/1/2015. (TN 1580) (CR9252)

## - National Coverage Analyses (NCAs)

### National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.

- Original consideration for Screening DNA Stool Test for Colorectal Cancer (CAG-00144N)
- Original consideration for Screening for Colorectal Cancer - Stool DNA Testing (CAG-00440N)
- Original consideration for Screening Immunoassay Fecal-Occult Blood Test (CAG-00180N)

## - Coding Analyses for Labs (CALs)

### Coding Analyses for Labs (CALs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with CALs, from the Coding Analyses for Labs database.

- Original consideration for Prothrombin Time and Fecal Occult Blood (Revision of ICD-9-CM Codes for Injury to Gastrointestinal Tract) (CAG-00187N)

## - Additional Information

### Other Versions

- Colorectal Cancer Screening Tests - Version 4, Effective between 1/27/2014 - 10/9/2014
- Colorectal Cancer Screening Tests - Version 3, Effective between 5/12/2009 - 1/27/2014
- Colorectal Cancer Screening Tests - Version 2, Effective between 4/28/2008 - 5/12/2009
- Colorectal Cancer Screening Tests - Version 1, Effective between 1/1/2004 - 4/28/2008