

Colorectal Cancer Screening Tests (NCD 210.3)

Guideline Number: MPG056.06
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Policy Summary

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

Item/Service Description

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

Nationally Covered Indications

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.)

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).

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:

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

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
00811	Anesthesia for lower intestinal endoscopic procedures, endoscopy introduced distal to duodenum; not otherwise specified
00812	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy
74263	Computed tomographic (CT) colonography, screening, including image postprocessing (Non-Covered)
81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
82270	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided 3 cards or single triple card for consecutive collection)

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HCPCS Code	Description
G0104	Colorectal cancer screening; flexible sigmoidoscopy
G0105	Colorectal cancer screening; colonoscopy on individual at high risk
G0106	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema
G0120	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema
G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
G0122	Colorectal cancer screening; barium enema (Non-Covered)
G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous determinations

Modifier	Description
33	Preventive services
53	Discontinued procedure
PT	Colorectal cancer screening test; converted to diagnostic test or other procedure
QW	CLIA waived

References

CMS National Coverage Determinations (NCDs)

[NCD 210.3 Colorectal Cancer Screening Tests](#)

Reference NCD: [NCD 190.34 Fecal Occult Blood Test](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L33452 Virtual Colonoscopy CT (Colonography)	A56772 Billing and Coding: Virtual Colonoscopy (CT Colonography)	Palmetto		AL, GA, NC, SC, TN, VA, WV
L33562 Computed Tomographic (CT) Colonography for Diagnostic Uses	A57026 Billing and Coding: Computed Tomographic (CT) Colonography for Diagnostic Uses	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L34055 Virtual Colonoscopy (CT Colonography)	A56800 Billing and Coding: Virtual Colonoscopy (CT Colonography)	CGS	KY, OH	KY, OH
L34454 Colonoscopy/Sigmoidoscopy/P roctosigmoidoscopy	A55069 Billing and Coding: Screening Colonoscopy Converted to a Diagnostic and/or Therapeutic Colonoscopy	Palmetto	AL, GA, NC, SC, TN, VA, WV AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV AL, GA, NC, SC, TN, VA, WV
	A55227 Billing and Coding: Incomplete Colonoscopy/Failed Colonoscopy	Palmetto	AL, GA, NC, SC, TN, VA, WV AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV AL, GA, NC, SC, TN, VA, WV
N/A	A52378 Colorectal Cancer Screening – Medical Policy Article	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A56487 Diagnostic colonoscopy and colorectal cancer screening revisions to the Part A and Part B LCDs	First Coast	FL, PR, VI	FL, PR, VI
L33283 Computed Tomographic Colonography Retired 02/14/2020	A57652 Billing and Coding: Computed Tomographic Colonography Retired 02/14/2020	First Coast	FL, PR, VI	FL, PR, VI
N/A	A54885 Computed Tomographic Colonography coding guidelines Retired 07/24/2020	First Coast	FL, PR, VI	FL, PR, VI

CMS Benefit Policy Manual

[Chapter 13: § 50.2 FQHC Services, § 210.1.4 Copayment and Deductible for Preventive Health Services](#)

[Chapter 15: § 280.2 Colorectal Cancer Screening](#)

[Chapter 16: § 90 Routine Services and Appliances](#)

CMS Claims Processing Manual

[Chapter 12: § 30.1 B. Incomplete Colonoscopies \(Codes 44388, 45378, G0105 and G0121\)](#)

[Chapter 18: § 60 Colorectal Cancer Screening](#)

[Chapter 19: § 80.5 Carrier-Screening and Preventive Services, § 100.13 FI-Other Screening and Preventive Services - Payment Policy](#)

CMS Transmittal(s)

[Transmittal 176, Change Request 8881, Dated 10/17/2014 \(Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms \(AAA\) and Screening Fecal-Occult Blood Tests \(FOBT\)\)](#)

[Transmittal 183, Change Request 9115, Dated 08/06/2015 \(National Coverage Determination \(NCD\) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test\)](#)

[Transmittal 1537, Change Request 9252, Dated 08/21/2015 \(ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations \(NCDs\)–3rd Maintenance CR\)](#)

[Transmittal 1580, Change Request 9252, Dated 12/03/2015 \(ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations \(NCDs\)–3rd Maintenance CR\)](#)

[Transmittal 1658, Change Request 9540, Dated 04/29/2016 \(Coding Revisions to National Coverage Determinations\)](#)

[Transmittal 1665, Change Request 9631, Dated 05/13/2016 \(Coding Revisions to National Coverage Determinations\) \(NCDs\)](#)

[Transmittal 1672, Change Request 9631, Dated 06/03/2016 \(Coding Revisions to National Coverage Determinations \(NCDs\)\)](#)

[Transmittal 1755, Change Request 9861, Dated 11/18/2016 \(ICD-10 Coding Revisions to National Coverage Determination \(NCDs\)\)](#)

[Transmittal 1792, Change Request 9861, Dated 02/03/2017 \(ICD-10 Coding Revisions to National Coverage Determination \(NCDs\)\)](#)

[Transmittal 2033, Change Request 10473, Dated 02/16/2018 \(ICD-10 and Other Coding Revisions to National Coverage Determinations \(NCDs\)\)](#)

[Transmittal 2039, Change Request 10473, Dated 02/28/2018 \(ICD-10 and Other Coding Revisions to National Coverage Determinations \(NCDs\)\)](#)

[Transmittal 2382, Change Request 11491, Dated 11/01/2019 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–April 2020 Update\)](#)

[Transmittal 2427, Change Request 11491, Dated 02/04/2020 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–April 2020 Update\)](#)

[Transmittal 3096, Change Request 8881, Dated 10/17/2014 \(Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms \(AAA\) and Screening Fecal-Occult Blood Tests \(FOBT\)\)](#)

[Transmittal 3436, Change Request 9115, Dated 12/30/2015 \(National Coverage Determination \(NCD\) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test\)](#)

[Transmittal 3763, Change Request 10075, Dated 04/28/2017 \(Payment for Moderate Sedation Services Furnished with Colorectal Cancer Screening Tests\)](#)
[Transmittal 3848, Change Request 10199, Dated 08/25/2017 \(Updates to Pub. 100-04, Chapter 18 Preventive and Screening Services and Chapter 32 Billing Requirements for Special Services and Publication 100-03, Chapter 1 Coverage Determinations Part 4\)](#)
[Transmittal 3844, Change Request 10181, Dated 08/18/2017 \(Replacement of Mammography HCPCS Codes, Waiver of Coinsurance and Deductible for Preventive and Other Services, and Addition of Anesthesia and Prolonged Preventive Services\)](#)
[Transmittal 4153, Change Request 10937, Dated 10/26/2018 \(Incomplete Colonoscopies Billed with Modifier 53 for Critical Access Hospital \(CAH\) Method II Providers\)](#)

MLN Matters

[Article MM8109, International Classification of Diseases 10th Edition \(ICD-10\) Conversion from ICD-9 and Related Code Infrastructure of the Medicare Shared Systems as They Relate to the Centers for Medicare & Medicaid Services \(CMS\) National Coverage Determinations \(NCDs\)](#)
[Article MM8874, Revised, Preventive and Screening Services - Update - Intensive Behavioral Therapy for Obesity, Screening Digital Tomosynthesis Mammography, and Anesthesia Associated with Screening Colonoscopy](#)
[Article MM8881, Medicare Coverage of Ultrasound Screening for Abdominal Aortic Aneurysms \(AAA\) and Screening Fecal-Oculta Blood Tests \(FOBT\)](#)
[Article MM9115, Revised, National Coverage Determination \(NCD\) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test](#)
[Article MM10075, Payment for Moderate Sedation Services Furnished with Colorectal Cancer Screening Tests](#)
[Article MM10181, Replacement of Mammography HCPCS Codes, Waiver of Coinsurance and Deductible for Preventive and Other Services, and Addition of Anesthesia and Prolonged Preventive Services](#)
[Article MM11491 Revised, International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–April 2020 Update](#)
[Article SE0613, Colorectal Cancer: Preventable, Treatable, and Beatable: Medicare Coverage and Billing for Colorectal Cancer Screening](#)

UnitedHealthcare Commercial Policies

[Computed Tomographic Colonography](#)
[Preventive Care Services](#)

Other(s)

[Decision Memo for Screening for Colorectal Cancer - Stool DNA Testing \(CAG-00440N\), CMS Website](#)
[Medicare Provides Coverage for Certain Colorectal Cancer Screenings, Colorectal Cancer Awareness Month, Dated 03/13/2014, CMS Website](#)
[Public Meeting for the Laboratory Payment for New Clinical Test Codes for 2016, Laboratory Public Meetings, CMS Website](#)
[Medicare Preventive Services, MLN 006559, August 2020](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none"> Reformatted policy; transferred content to new template
10/14/2020	Policy Summary <ul style="list-style-type: none"> Reorganized and revised language to indicate: <i>Item/Service Description General</i> <ul style="list-style-type: none"> Sections 1861(s)(2)(R) and 1861(pp) of the Social Security Act (the Act) and regulations at 42 Code of Federal Regulations (CFR) 410.37 authorize Medicare coverage for screening colorectal cancer tests under Medicare Part B

Date	Summary of Changes
	<ul style="list-style-type: none"> • 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 <p><i>Nationally Covered Indications</i></p> <p>Fecal Occult Blood Tests (effective January 1, 2004)</p> <ul style="list-style-type: none"> • Fecal occult blood tests (FOBTs) are generally divided into two types: immunoassay and guaiac types <ul style="list-style-type: none"> ○ Immunoassay (or immunochemical) fecal occult blood tests (iFOBT) use antibodies directed against human globin epitopes <ul style="list-style-type: none"> ▪ 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 <ul style="list-style-type: none"> ▪ 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 (CMS) evaluated colorectal cancer screening using immunoassay FOBTs in general • Effective for dates of service on and after Jan. 1, 2004, Medicare covers one screening FOBT per annum for the early detection of colorectal cancer <ul style="list-style-type: none"> ○ 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 <p>The Cologuard™ - Multitarget Stool DNA (sDNA) Test (effective October 9, 2014)</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ 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 Oct. 9, 2014, The Cologuard™ test is covered once every three years for Medicare beneficiaries that meet all of the following criteria: <ul style="list-style-type: none"> ○ Age 50 to 85 years; and,

Date	Summary of Changes
	<ul style="list-style-type: none"> ○ 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) <p><i>Nationally Non-Covered Indications</i></p> <ul style="list-style-type: none"> ● All other indications for colorectal cancer screening not otherwise specified in the Act and regulations, or otherwise specified [in the policy] remain nationally non-covered ● Non-coverage specifically includes: <ul style="list-style-type: none"> ○ All screening sDNA tests, effective Apr. 28, 2008, through Oct. 8, 2014 <ul style="list-style-type: none"> ▪ Effective for dates of service on or after Oct. 9, 2014, all other screening sDNA tests not otherwise specified [in the policy] remain nationally non-covered ○ Screening computed tomographic colonography (CTC), effective May 12, 2009 <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>References</i> section to reflect the most current information ● Archived previous policy version MPG056.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage

Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).