

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10818</b>	<b>Date: May 20, 2021</b>
	<b>Change Request 12280</b>

**SUBJECT: National Coverage Determination (NCD) 210.3 - Screening for Colorectal Cancer (CRC)-Blood-Based Biomarker Tests**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform contractors that CMS has determined effective on January 19, 2021 blood-based biomarker test is an appropriate colorectal cancer screening test based on specific criteria. The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (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: January 19, 2021**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: October 4, 2021**

*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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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: 10818	Date: May 20, 2021	Change Request: 12280
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**EFFECTIVE DATE: January 19, 2021**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: October 4, 2021**

## 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.

Over the last several years, blood-based biomarker tests have emerged as another potential non-invasive option for the early detection of colorectal cancer. A blood-based biomarker (biological marker in the patient's blood) is a measurable DNA, RNA or protein component that indicates disease, in this case cancer. For example, blood-based cancer biomarkers include but are not limited to specific gene mutations, methylation of genes, and antigens. The blood-based biomarker that is measured in a person's blood can be an indicator of a process, such as disease risk or progression, like progression to colorectal cancer, thought to be correlated with a long term outcome, such as mortality.

**B. Policy:** Effective for services performed on or after January 19, 2021, CMS has determined that a blood-based biomarker test is an appropriate colorectal cancer screening test once every 3 years for Medicare beneficiaries when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

The patient is:

- age 50-85 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 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, or hereditary nonpolyposis colorectal cancer).

The blood-based biomarker screening test must have all of the following:

- FDA market authorization with an indication for colorectal cancer screening; and
- proven test performance characteristics for a blood-based screening test with both sensitivity greater than or equal to 74% and specificity 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 pivotal studies included in the FDA labeling.

## II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility										
		A/B MAC			D M E	Shared-System Maintainers				Other		
		A	B	H H H		F M V C	M C M S	V M S S	C W F			
12280 - 03.1	<p>Effective for dates of service on and after January 19, 2021, CMS has determined that a blood-based biomarker test is an appropriate colorectal cancer screening test based on specific criteria.</p> <p>Please refer to Pub.100-03 NCD Manual, Section 210.3 for further coverage policy and Pub.100-04 Claims Processing Manual, Chapter 18, Section 60, for claims processing instructions.</p>	X	X									

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC			D M E	C E D I		
		A	B	H H H			M A C	
12280 - 03.2	<p>MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.</p>	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:
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**Section B: All other recommendations and supporting information:** N/A

**V. CONTACTS**

**Pre-Implementation Contact(s):** William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims Processing) , Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage and Analysis) , Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims Processing) , Wendy Knarr, 410-786-0843 or Wendy.Knarr@cms.hhs.gov (Supplier Claims Processing) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis)

**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: 1**

## **210.3 – Colorectal Cancer Screening Tests**

**(Rev. 10818; Issued: 05-20-21; Effective: 01-09-21; Implementation: 10-04-21)**

### **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) (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 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 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™ – Multi-target 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™ – multi-target 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).

### ***3. Blood-based Biomarker Tests (effective January 19, 2021)***

*Blood-based DNA testing detects molecular markers of altered DNA that are contained in the cells shed into the blood by colorectal cancer and pre-malignant colorectal epithelial neoplasia.*

*Effective for dates of service on or after January 19, 2021, a blood-based biomarker test is covered as an appropriate colorectal cancer screening test once every 3 years for Medicare beneficiaries when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:*

*The patient is:*

- *age 50-85 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 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, or hereditary nonpolyposis colorectal cancer).*

*The blood-based biomarker screening test must have all of the following:*

- *Food and Drug Administration (FDA) market authorization with an indication for colorectal cancer screening; and,*
- *proven test performance characteristics for a blood-based screening test with both sensitivity greater than or equal to 74% and specificity greater than or equal to 90% in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), as minimal threshold levels, based on the pivotal studies included in the FDA labeling.*

### **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 was last reviewed January 2021.)*



<b>NCD:</b>	210.3
<b>NCD Title:</b>	Colorectal Cancer Screening Tests
<b>IOM:</b>	<a href="http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf">www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf</a>
<b>MCD:</b>	<a href="http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&amp;ncdver=3&amp;CoverageSelection=National&amp;bc=gAAACAAAA&amp;">http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&amp;ncdver=3&amp;CoverageSelection=National&amp;bc=gAAACAAAA&amp;</a>
<b>CPM:</b>	<a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf">http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf</a>
<b>ICD-10 CM</b>	<b>ICD-10 DX Description</b>
	<b>CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.</b>
	<b>Partial List of Dx Codes Indicating High Risk: Only applicable to G0105 and G0120 (high risk colorectal screening)</b>
C18.0	Malignant neoplasm of cecum
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C49.A5	Gastrointestinal stromal tumor of rectum
C78.5	Secondary malignant neoplasm of large intestine and rectum
C7A.021	Malignant carcinoid tumor of the cecum
C7A.022	Malignant carcinoid tumor of the ascending colon
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colon
C7A.025	Malignant carcinoid tumor of the sigmoid colon
C7A.026	Malignant carcinoid tumor of the rectum
D01.0	Carcinoma in situ of colon
D01.1	Carcinoma in situ of rectosigmoid junction
D01.2	Carcinoma in situ of rectum
D01.3	Carcinoma in situ of anus and anal canal
D12.0	Benign neoplasm of cecum
D12.2	Benign neoplasm of ascending colon
D12.3	Benign neoplasm of transverse colon
D12.4	Benign neoplasm of descending colon
D12.5	Benign neoplasm of sigmoid colon
D12.7	Benign neoplasm of rectosigmoid junction
D12.8	Benign neoplasm of rectum
D12.9	Benign neoplasm of anus and anal canal
D37.4	Neoplasm of uncertain behavior of colon
D37.5	Neoplasm of uncertain behavior of rectum
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D3A.021	Benign carcinoid tumor of the cecum
D3A.022	Benign carcinoid tumor of the ascending colon
D3A.023	Benign carcinoid tumor of the transverse colon

ICD-10 CM	ICD-10 DX Description
D3A.024	Benign carcinoid tumor of the descending colon
D3A.025	Benign carcinoid tumor of the sigmoid colon
D3A.026	Benign carcinoid tumor of the rectum
D3A.029	Benign carcinoid tumor of the large intestine, unspecified portion
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess

ICD-10 CM	ICD-10 DX Description
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis
K52.89	Other specified noninfective gastroenteritis and colitis
K52.9	Noninfective gastroenteritis and colitis, unspecified
K57.20	Diverticulitis of large intestine with perforation and abscess without bleeding
K57.21	Diverticulitis of large intestine with perforation and abscess with bleeding
K57.30	Diverticulosis of large intestine without perforation or abscess without bleeding
K57.31	Diverticulosis of large intestine without perforation or abscess with bleeding
K57.32	Diverticulitis of large intestine without perforation or abscess without bleeding
K57.33	Diverticulitis of large intestine without perforation or abscess with bleeding
K57.40	Diverticulitis of both small and large intestine with perforation and abscess without bleeding
K57.41	Diverticulitis of both small and large intestine with perforation and abscess with bleeding
K57.50	Diverticulosis of both small and large intestine without perforation or abscess without bleeding
K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding
K57.52	Diverticulitis of both small and large intestine without perforation or abscess without bleeding
K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding
K57.80	Diverticulitis of intestine, part unspecified, with perforation and abscess without bleeding
K57.81	Diverticulitis of intestine, part unspecified, with perforation and abscess with bleeding
K57.90	Diverticulosis of intestine, part unspecified, without perforation or abscess without bleeding
K57.91	Diverticulosis of intestine, part unspecified, without perforation or abscess with bleeding
K57.92	Diverticulitis of intestine, part unspecified, without perforation or abscess without bleeding
K57.93	Diverticulitis of intestine, part unspecified, without perforation or abscess with bleeding

ICD-10 CM	ICD-10 DX Description
K62.0	Anal polyp
K62.1	Rectal polyp
K62.6	Ulcer of anus and rectum
K63.3	Ulcer of intestine
K63.5	Polyp of colon
Z12.10	Encounter for screening for malignant neoplasm of intestinal tract, unspecified
Z12.11	Encounter for screening for malignant neoplasm of colon
Z12.12	Encounter for screening for malignant neoplasm of rectum
Z15.09	Genetic susceptibility to other malignant neoplasm
Z80.0	Family history of malignant neoplasm of digestive organs
Z83.71	Family history of colonic polyps
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.048	Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus
Z86.004	Personal history of in-situ neoplasm of other and unspecified digestive organs
Z86.010	Personal history of colonic polyps
<b>Applicable to 81528 and G0327- only 1 dx required</b>	
Z12.12	Encounter for screening for malignant neoplasm of rectum
Z12.11	Encounter for screening for malignant neoplasm of colon

<b>NCD:</b>	210.3	
<b>NCD Title:</b>	Colorectal Cancer Screening Tests	
<b>IOM:</b>	<a href="http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf">www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf</a>	
<b>MCD:</b>	<a href="http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&amp;ncdver=3&amp;CoverageSelection=National&amp;bc=qAAAACAAAA&amp;">http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&amp;ncdver=3&amp;CoverageSelection=National&amp;bc=qAAAACAAAA&amp;</a>	
<b>ICD-10</b>	<b>ICD-10 PCS Description</b>	
N/A	N/A	
	<b>CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.</b>	

Propose d HCPCS CPT Part A	Frequency Limitations	T OB Part A	Revenue Code Part A	Modifier Part A	Provider Specialty	MSN Message Part A	CARC Message Part A	RARC Message Part A
<p><b>Part A</b></p> <p><b>Rule Description Part A</b></p> <p>Effective 1/1/08, payment may be made for colorectal cancer screening by early detection of cancer. For screening colonoscopy services (1 type of service included in benefit) prior to 7/1/01, coverage was limited to high-risk individuals. Effective 7/1/01, screening colonoscopies are covered for individuals not at high-risk. CWF shall not bill for colorectal screening claims for age &amp; frequency. CWF will not AMAC claims for valid procedure codes (G0104, G0105, G0106, G2770, G0120, G0121, G0122, and G0328) and for valid T OBs.</p>								
G0104 G0105 G0106 G2770 G0120 G0121	varies by CPT HCPCS	varies by HCPCS	varies by CPT HCPCS	N/A	N/A	varies by risk see below	varies by risk see below	varies by risk see below
<p><b>Part A</b></p> <p><b>FIS &amp; AMACs:</b> Shall allow approved G0104, G0106, G2770, G0328 for ages 50 years and older. Screening flexible sigmoidoscopy, G0106, may be paid for beneficiaries who have attained age 50. Effective 1/1/08, screening FOBT, G2770*, G0107*, may be paid for beneficiaries who have attained age 50. Effective 1/1/04, screening FOBT, G0328, may be paid as an alternative to G2770*, G0107*, for beneficiaries who have attained age 50.</p>								
G0104 G0106 G0328	N/A	N/A	N/A	N/A	N/A	18.13 18.15	86	M82
<p><b>Part A</b></p> <p><b>FIS &amp; AMACs:</b> Shall allow FOBT G2770 or G0328 (as an alternative to G2770) <b>once per 48 months</b> (i.e., at least 11 months have passed following month in which last covered screening FOBT was performed). Effective 1/1/04, payment may be made for immunoassay-based FOBT, G0328, as an alternative to guaiac-based FOBT, G2770*. Medicare will pay for only one covered FOBT per year, either G2770* or G0328, but not both.</p>								
G2770 G0328	1 x 12 months	12X 13X 14X* Only for non-patient lab specimens	85X 030X	N/A	N/A	18.14 18.16	119	M90 N386
<p><b>Part A</b></p> <p><b>AMACs:</b> Shall allow G0104 when performed by doctor of medicine/sociology, or by PA, NP, or CNS (as defined in 11861(a)(3) &amp; CFR 42 CFR 410.74, 410.75, 410.76) at frequency of <b>1 every 48 months</b> (i.e., at least 47 months have passed following month in which last covered screening flexible sigmoidoscopy was done) unless beneficiary does not meet criteria for high-risk (refer to 950.3) and he/she has had screening colonoscopy, G0121, within preceding 10 years. If screening colonoscopy within preceding 10 years, then he/she can have screening flexible sigmoidoscopy only after at least 119 months have passed following month that he/she received screening colonoscopy, G0121.</p>								
G0104	1 x 48 months	12X 13X 22X	85X* TC	N/A	N/A	18.14 18.16	119	M86 N386
<p><b>Part A</b></p> <p><b>FIS &amp; AMACs:</b> Shall allow G0106 at frequency of <b>one every 48 months</b>, i.e., at least 47 months have passed following month in which last screening barium enema or screening flexible sigmoidoscopy was performed. Screening barium enema requires written order from beneficiary's attending physician.</p>								
G0106	1 per 48 months	12X 13X 22X	85X* RCI for TC	N/A	N/A	18.14 18.16	119	M86
<p><b>Part A</b></p> <p><b>AMACs:</b> Shall allow screening colonoscopies, G0105 with <b>signature</b> when performed by doctor of medicine/sociology at frequency of <b>1 every 24 months</b> for beneficiaries at <b>high-risk</b> (i.e., at least 23 months have passed following month in which last covered G0105 screening colonoscopy was performed). <b>NOTE:</b> There may be more instances of conditions, which may be coded and could be considered high-risk at AMAC discussion. This edit shall be overrideable. Additional dx will be MAC discussion. R/Cs: 99999/9100.</p>								
G0105	1 x 24 months	12X 13X 22X 83X 85X* TC	85X* TC	N/A	N/A	18.14 18.16	119	M83 M86
<p><b>Part A</b></p> <p><b>AMACs:</b> Shall allow G0120 as alternative to G0105 with <b>signature</b> <b>once every 24 months</b> (i.e., at least 23 months have passed following month in which last screening barium enema or last screening colonoscopy was performed, must have written order from beneficiary's attending physician. <b>NOTE:</b> There may be more instances of conditions, which may be coded and could be considered high-risk at medical director's discretion. This edit shall be overrideable. Additional dx at MAC discussion. R/Cs: 99999/9100.</p>								
G0120	1 x 24 months	12X 13X 22X	85X* RCI for TC	N/A	N/A	18.14 18.16	119	M83 M86
<p><b>Part A</b></p> <p><b>FIS &amp; AMACs:</b> Shall allow <b>once every 10 years</b> (i.e., at least 119 months have passed following month in which last covered G0121 screening colonoscopy was performed. If individual does not otherwise qualify to have G0121 screening colonoscopy based on above see 9100.2.1) and 2) but has had covered screening flexible sigmoidoscopy, G0104, then he/she may have G0121 screening colonoscopy only after at least 47 months have passed following month in which last covered G0104 flexible sigmoidoscopy was performed. <b>NOTE:</b> If during screening colonoscopy, a polyps/growth is detected which results in biopsy/removal of growth, appropriate is procedure classified as colonoscopy with biopsy/removal should be billed and paid rather than G0121.</p>								
G0121	1 x 10 yrs for average risk patients 1 x 2 years for high-risk patients	12X 13X 22X 83X 85X* TC	85X* TC	N/A	N/A	18.14 18.16	119	M86 N386
<p><b>Part A</b></p> <p><b>FIS &amp; AMACs:</b> Shall deny G0122 &amp; 74263 as <b>non-covered</b> because they fail to meet benefit requirements. Beneficiary is liable for payment. Codes are not covered by Medicare.</p>								
G0122 74263	N/A	12X 13X 22X	85X* RCI for TC	N/A	N/A	18.10	68	N420
<p><b>Part A</b></p> <p><b>FIS, AMACs, CWF:</b> Effective 10/9/14, shall allow Cologuard™ test G0464, and Effective 1/1/9/21, allow Blood-Based Biomarker tests using genetic G0327 unless a more specific code becomes available (G0327 effective 7/1/21) for approved at <b>every 3 years</b> for beneficiaries who meet all the following criteria: - Age 45-54 years. - Asymptomatic (no signs/symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac FOBT 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 an adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer). Only one diagnosis J11.11 OR J12.12 is required on the claim. Effective for claims with DOS on and after 1/1/16, G0464 shall not be included with 9100. <b>NOTE:</b> Deductible and coinsurance are waived.</p>								
B1528 G0327	1 x 3 yrs	N/A	N/A	N/A	N/A	18.10 18.20 21.25	119 8 167	N386 N129 N386 N386
<p><b>Part A</b></p> <p><b>FIS, AMACs:</b> For colorectal cancer screening, effective 1/1/16, when anesthesia 00812 is performed in conjunction with screening colonoscopy G0105 or G0121, coinsurance and deductible will be waived for anesthesia 00812. When screening colonoscopy becomes de colonoscopy, anesthesia 00811 should be submitted with only -PT modifier and only deductible will be waived.</p>								
00811 (dx) 00812 166	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

