

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10818	Date: May 20, 2021
	Change Request 12280

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.

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	18/1.2/Table of Preventive and Screening Services
R	18/60/Colorectal Cancer (CRC) Screening
R	18/60/1/ Payment
R	18/60/1/1/Deductible and Coinsurance
R	18/60/2/HCPCS Codes, Frequency Requirements, and Age Requirements
R	18/60/2/1/CWF Edits
R	18/60/2/2/Ambulatory Surgical Center (ASC) Facility Fee
R	18/60/3/Determining High Risk for Developing CRC
R	18/60/5/Non-Covered Services
R	18/60/6/Billing Requirements for Claims Submitted to A/B MACs (A)
R	18/60/7/Medicare Summary Notice (MSN) Messages
R	18/60/8/Remittance Advice Codes

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. 100-04	Transmittal: 10818	Date: May 20, 2021	Change Request: 12280
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SUBJECT: National Coverage Determination (NCD) 210.3 - Screening for Colorectal Cancer (CRC)-Blood-Based Biomarker Tests

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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 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 M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
12280 - 04.1	<p>Effective for claims with dates of service on or after January 19, 2021, contractors shall recognize new HCPCS code G0327 (Colorectal cancer screening; blood-based biomarker) as a covered service.</p> <p>NOTE: HCPCS G0327 is in the July 1, 2021 Clinical Laboratory Fee Schedule (CLFS) update with an effective date of July 1, 2021, and in the July 2021 Integrated Outpatient Code Editor (IOCE) update with an effective date of July 1, 2021.</p> <p>NOTE: Refer to Publication (Pub.) 100-03, Medicare National Coverage Determination Manual, Chapter 1, Section 210.3 for coverage policy, and Pub. 100-04, Claims Processing Manual, Chapter 18, Section 60, for claims processing instructions.</p>	X	X			X				IOCE	
12280 - 04.1.1	Effective for claims with dates of service on and after January 19, 2021, Medicare deductible and coinsurance shall be waived for HCPCS G0327.	X	X								
12280 - 04.2	Effective for claims with dates of service on or after January 19, 2021, contractors shall deny line-items on claims containing HCPCS G0327 when reported more than once in a 3-year period [at least 2 years and 11 full months (35 months total) must elapse from the date of the last screening].		X			X				X	
12280 - 04.2.1	<p>When denying a line-item on a claim per requirement 12280-04.2, contractors shall use the following messages:</p> <p>CARC 119: "Benefit maximum for this time period or occurrence has been reached."</p> <p>RARC N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available</p>	X	X								

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared- System Maintainers				Other	
		A	B	H H H		F M V C	M I C S	V M S	C W F		
	<p>at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”</p> <p>Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.</p>										
12280 - 04.2.1.1	<p>(Continuation of 12280-04.2.1)</p> <p>(Part A only) MSN 15.19: “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor.”</p> <p>Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.</p> <p>MSN 15.20: “The following policies NCD 210.3 were used when we made this decision.”</p> <p>Spanish Version – “Las siguientes políticas NCD 210.3 fueron utilizadas cuando se tomó esta decisión.”</p> <p>NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.</p>	X	X								
12280 - 04.2.1.2	The contractor shall ensure the new CWF edit is associated with a new 59CXX line level reason code and the new 59CXX will auto-assign during Medical					X					

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
	Policy in place of the FISS UXXXX line level reason code.										
12280 - 04.3	Effective for claims with dates of service on or after January 19, 2021, contractors shall deny line-items on claims containing HCPCS code G0327 when the beneficiary is not between ages of 50-85 on the date of service.							X			X
12280 - 04.3.1	<p>When denying a line-item on a claim per requirement 12280-04.3, contractors shall use the following messages:</p> <p>CARC 6: “The procedure/revenue code is inconsistent with the patient's age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”</p> <p>RARC N129: “Not eligible due to the patient’s age.”</p> <p>(Part A only) MSN 15.19: “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor.”</p> <p>Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.</p> <p>MSN 15.20: “The following policies NCD 210.3 were used when we made this decision.”</p> <p>Spanish Version – “Las siguientes políticas NCD 210.3 fueron utilizadas cuando se tomó esta decisión.”</p>	X	X								

Number	Requirement	Responsibility								Other
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				
		A	B			F I S S	M C S	V M S	C W F	
	<p>NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.</p> <p>Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.</p>									
12280 - 04.3.2	The contractor shall ensure the new CWF edit is associated with a new 59CXX line level reason code and the new 59CXX will auto-assign during Medical Policy in place of the FISS UXXXX line level reason code.					X				
12280 - 04.4	<p>Effective for claims with dates of service on or after January 19, 2021, contractors shall deny line-items on claims containing HCPCS code G0327 when the claim does not contain ONE of the International Classification of Disease -10 diagnosis codes listed below:</p> <p>Z12.12 OR Z12.11</p>					X	X			
12280 - 04.4.1	<p>When denying a line-item on a claim per requirement 12280 - 04.4, contractors shall use the following messages:</p> <p>CARC 167 – This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC N386 – “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have</p>	X	X							

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
	<p>web access, you may contact the contractor to request a copy of the NCD.”</p> <p>Group Code CO assigning financial liability to the provider, if a claim is received with a GZ</p>										
12280 - 04.4.1.1	<p>(Continuation of BR 12280-04.4.1):</p> <p>(Part A only): MSN 15.19: “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor.”</p> <p>Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.</p> <p>MSN 15.20: “The following policies NCD 210.3 were used when we made this decision.” Spanish Version – “Las siguientes políticas NCD 210.3 fueron utilizadas cuando se tomó esta decisión.”</p> <p>NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.</p>	X	X								
12280 - 04.5	Contractors shall only pay for HCPCS code G0327 claims on Type of Bill (TOB) 13X, 14X, and 85X.					X					
12280 - 04.5.1	Contractors shall pay for HCPCS code G0327 on institutional claims in hospital outpatient departments (TOB 13X) and hospital non-patient laboratories (14X) based on the CLFS. Payment for critical access hospitals (CAHs, TOB 85X) is based on reasonable cost.	X				X					

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
	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.					

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): Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Patricia BrocatoSimons, 410-786-0261 or Patricia.BrocatoSimons@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) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims Processing)

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

Medicare Claims Processing Manual

Chapter 18 - Preventive and Screening Services

1.2 – Table of Preventive and Screening Services

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

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
Initial Preventive Physical Examination, IPPE	G0402	Initial preventive physical examination; face to face visits, services limited to new beneficiary during the first 12 months of Medicare enrollment	*Not Rated	WAIVED
	G0403	Electrocardiogram, routine ECG with 12 leads; performed as a screening for the initial preventive physical examination with interpretation and report		Not Waived
	G0404	Electrocardiogram, routine ECG with 12 leads; tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination		Not Waived
	G0405	Electrocardiogram, routine ECG with 12 leads; interpretation and report only, performed as a screening for the initial preventive physical examination		Not Waived

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
Ultrasound Screening for Abdominal Aortic Aneurysm (AAA) services furnished prior to January 1, 2017	G0389	Ultrasound, B-scan and /or real time with image documentation; for abdominal aortic aneurysm (AAA) ultrasound screening	B	WAIVED
Ultrasound Screening for Abdominal Aortic Aneurysm (AAA) services furnished on or after January 1, 2017	76706	Ultrasound, abdominal aorta, real time with image documentation, screening study for abdominal aortic aneurysm (AAA)	B	WAIVED
Cardiovascular Disease Screening	80061	Lipid panel	A	WAIVED
	82465	Cholesterol, serum or whole blood, total		WAIVED
	83718	Lipoprotein, direct measurement; high density cholesterol (hdl cholesterol)		WAIVED
	84478	Triglycerides		WAIVED

Diabetes Screening Tests	82947	Glucose; quantitative, blood (except reagent strip)	B	WAIVED
	82950	Glucose; post glucose dose (includes glucose)		WAIVED
Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	82951	Glucose; tolerance test (gtt), three specimens (includes glucose)	*Not Rated	WAIVED
Diabetes Self-Management Training Services (DSMT)	G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	*Not Rated	Not Waived
	G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes		Not Waived
Medical Nutrition Therapy (MNT) Services	97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes	B	WAIVED
	97803	Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes		WAIVED
	97804	Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes		WAIVED

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	G0270	Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face to face with the patient, each 15 minutes	B	WAIVED
	G0271	Medical nutrition therapy, reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition, or treatment regimen (including additional hours needed for renal disease), group (2 or more individuals), each 30 minutes		WAIVED
Screening Pap Test	G0123	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, screening by cytotechnologist under physician supervision	A	WAIVED
	G0124	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician		WAIVED

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	G0141	Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician	A	WAIVED
	G0143	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual screening and rescreening by cytotechnologist under physician supervision	A	WAIVED
	G0144	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system, under physician supervision	A	WAIVED
	G0145	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system and manual rescreening under physician supervision	A	WAIVED
	G0147	Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision	A	WAIVED

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	G0148	Screening cytopathology smears, cervical or vaginal, performed by automated system with manual rescreening	A	WAIVED
	P3000	Screening papanicolaou smear, cervical or vaginal, up to three smears, by technician under physician supervision		WAIVED
	P3001	Screening papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician		WAIVED
	Q0091	Screening papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory		WAIVED
Screening Pelvic Exam	G0101	Cervical or vaginal cancer screening; pelvic and clinical breast examination	A	WAIVED
Screening Mammography	77052	Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; screening mammography (list separately in addition to code for primary procedure)	B	WAIVED
	77057	Screening mammography, bilateral (2-view film study of each breast)	B	WAIVED

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	77063	Screening digital breast tomosynthesis, bilateral		WAIVED
	77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed		WAIVED
Bone Mass Measurement	G0130	Single energy x-ray absorptiometry (sexa) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)	B	WAIVED
	77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)		WAIVED
	77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)		WAIVED
	77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)		WAIVED
	77081	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)		WAIVED

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	77083	Radiographic absorptiometry (e.g., photo densitometry, radiogrammetry), 1 or more sites		WAIVED
	77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites, axial skeleton, (e.g., hips, pelvis, spine), including vertebral fracture assessment.		WAIVED
	76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method		WAIVED
<p>NOTE:</p> <p>Anesthesia services furnished in conjunction with and in support of a screening colonoscopy are reported with CPT code 00812 and coinsurance and deductible are waived. When a screening colonoscopy becomes a diagnostic colonoscopy, anesthesia services are reported with CPT code 00811 and with the PT modifier; only the deductible is waived.</p>				
<p>Coinsurance and deductible are waived for moderate sedation services (reported with G0500 or 99153) when furnished in conjunction with and in support of a screening colonoscopy service and when reported with modifier 33. When a screening colonoscopy becomes a diagnostic colonoscopy, moderate sedation services (G0500 or 99153) are reported with only the PT modifier; only the deductible is waived.</p>				
Colorectal Cancer Screening	G0104	Colorectal cancer screening; flexible sigmoidoscopy	A	WAIVED

	G0105	Colorectal cancer screening; colonoscopy on individual at high risk		WAIVED
	G0106	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema	*Not Rated	Coins Applies, Deductible is waived
	G0120	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema.		Coins Applies, Deductible is waived

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk	A	WAIVED
	82270	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; feces, consecutive		WAIVED
	G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous		WAIVED

	81528	<i>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</i>		<i>WAIVED</i>
	G0327	<i>Colorectal cancer screening; blood-based biomarker Colon ca scrn;bld-bsd biomrk</i>		<i>WAIVED</i>
Prostate Cancer Screening	G0102	Prostate cancer screening; digital rectal examination	D	Not Waived
	G0103	Prostate cancer screening; prostate specific antigen test (PSA)		WAIVED
Glaucoma Screening	G0117	Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist	I	Not Waived
	G0118	Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist		Not Waived

Influenza Virus Vaccine		For the Medicare-covered codes for the influenza vaccines approved by FDA for current influenza vaccine season, please go to: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html		
	90630	Influenza virus vaccine, quadrivalent (IIV4), split virus, preservative free, for intradermal use	B	WAIVED

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	90653	Influenza virus vaccine, inactivated, subunit, adjuvanted, for intramuscular use		WAIVED
	90654	Influenza virus vaccine, split virus, preservative free, for intradermal use, for adults ages 18-64		WAIVED
	90655	Influenza virus vaccine, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular use		WAIVED
	90656	Influenza virus vaccine, split virus, preservative free, when administered to individuals 3 years and older, for intramuscular use		WAIVED

	90657	Influenza virus vaccine, split virus, when administered to children 6- 35 months of age. for intramuscular use		WAIVED
	90658	Influenza virus vaccine, trivalent (IIV3), split virus, 0.5 mL dosage, for intramuscular use		WAIVED
	90660	Influenza virus vaccine, live, for intranasal use		WAIVED
	90661	Influenza virus vaccine, derived from cell cultures, subunit, preservative and antibiotic free, for intramuscular use		WAIVED
Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use		WAIVED
	90672	Influenza virus vaccine, live, quadrivalent, for intranasal use		WAIVED
	90673	Influenza virus vaccine, trivalent, derived from recombinant DNA (RIV3), hemagglutinin (HA) protein only, preservative and antibiotic free, for intramuscular use		WAIVED

	90674	Influenza virus vaccine, quadrivalent (ccIIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use		WAIVED
	90682	Influenza virus vaccine, quadrivalent (RIV4), derived from recombinant DNA, hemagglutinin (HA) protein only, preservative and antibiotic free, for intramuscular use		WAIVED
	90685	Influenza virus vaccine, quadrivalent, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular use		WAIVED
Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	90686	Influenza virus vaccine, quadrivalent, split virus, preservative free, when administered to individuals 3 years of age and older, for intramuscular use		WAIVED
	90687	Influenza virus vaccine, quadrivalent, split virus, when administered to children 6-35 months of age, for intramuscular use		WAIVED
	90688	Influenza virus vaccine, quadrivalent, split virus, when administered to individuals 3 years of age and older, for intramuscular use		WAIVED

	90694	<i>Influenza virus vaccine, quadrivalent (aIIV4), inactivated, adjuvanted, preservative free, 0.5 mL dosage, for intramuscular use</i>		<i>WAIVED</i>
	90756	Influenza virus vaccine, quadrivalent (ccIIV4), derived from cell cultures, subunit, antibiotic free, 0.5mL dosage, for intramuscular use		WAIVED
	G0008	Administration of influenza virus vaccine		WAIVED
Pneumococcal Vaccine	90670	Pneumococcal conjugate vaccine, 13 valent, for intramuscular use	B	WAIVED
	90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, when administered to individuals 2 years or older, for subcutaneous or intramuscular use		WAIVED
	G0009	Administration of pneumococcal vaccine		WAIVED
Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
Hepatitis B Vaccine	90739	Hepatitis B vaccine, adult dosage (2 dose schedule), for intramuscular use	A	WAIVED
	90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use		WAIVED

	90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use		WAIVED
	90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use		WAIVED
	90746	Hepatitis B vaccine, adult dosage, for intramuscular use		WAIVED
	90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use		WAIVED
	G0010	Administration of Hepatitis B vaccine	A	WAIVED
Hepatitis C Virus Screening	G0472	Screening for Hepatitis C antibody	B	WAIVED

Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
HIV Screening	G0432	Infectious agent antigen detection by enzyme immunoassay (EIA) technique, qualitative or semi-qualitative, multiple- step method, HIV-1 or HIV-2, screening	A	WAIVED

	G0433	Infectious agent antigen detection by enzyme- linked immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening		WAIVED
	G0435	Infectious agent antigen detection by rapid antibody test of oral mucosa transudate, HIV-1 or HIV-2 , screening		WAIVED
Smoking Cessation for services furnished prior to October 1, 2016	G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes	A	WAIVED
	G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient intensive, greater than 10 minutes		WAIVED
Smoking Cessation for services furnished on or after October 1, 2016	99406	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes	A	WAIVED
Service	CPT/ HCPCS	Long Descriptor	USPSTF Rating	Coins/ Deductible
	99407	Smoking and tobacco cessation counseling visit for the asymptomatic patient intensive, greater than 10 minutes		WAIVED

Annual Wellness Visit	G0438	Annual wellness visit, including PPPS, first visit	*Not Rated	WAIVED
	G0439	Annual wellness visit, including PPPS, subsequent visit		WAIVED
Intensive Behavioral Therapy for Obesity	G0447	Face-to-Face Behavioral Counseling for Obesity, 15 minutes	B	WAIVED
	G0473	Face-to-face behavioral counseling for obesity, group (2-10), 30 minute(s)		
Lung Cancer Screening	G0296	Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)	B	WAIVED
	G0297	Low dose CT scan (LDCT) for lung cancer screening		

60 - Colorectal Cancer Screening

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

See the Medicare Benefit Policy Manual, Chapter 15, and the Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Section 210.3 for Medicare Part B coverage requirements and effective dates of colorectal cancer screening services.

Effective for services furnished on or after January 1, 1998, payment may be made for colorectal cancer screening for the early detection of cancer. For screening colonoscopy services (one of the types of services included in this benefit) prior to July 2001, coverage was limited to high-risk individuals. For services July 1, 2001, and later, screening colonoscopies are covered for individuals not at high risk.

The following services are considered colorectal cancer screening services:

- Fecal-occult blood test (FOBT), 1-3 simultaneous determinations (guaiac-based);
- Flexible sigmoidoscopy;
- Colonoscopy; and,
- Barium enema

Effective for services on or after January 1, 2004, payment may be made for the following colorectal cancer screening service as an alternative for the guaiac-based FOBT, 1-3 simultaneous determinations:

- *FOBT*, immunoassay, 1-3 simultaneous determinations

Effective *for services on or after* October 9, 2014, payment may be made for colorectal cancer screening using the Cologuard™ multi-target sDNA test:

- *HCPCS G0464* (Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3).

Note: HCPCS code G0464 expired on December 31, 2015, and has been replaced in the 2016 CLFS with CPT code 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, *effective January 2, 2016*.

Effective for services on or after January 19, 2021, payment may be made for colorectal cancer using Blood-based DNA Testing:

- *Blood-based Biomarker Test, HCPCS G0327, effective July 1, 2021*

60.1 - Payment

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

Payment is under the MPFS except as follows:

- FOBTs [CPT 82270* (HCPCS G0107*) and HCPCS G0328] are paid under the CLFS except reasonable cost is paid to all non-outpatient prospective payment system (OPPS) hospitals, including Critical Access Hospitals (CAHs), but not Indian Health Service (IHS) hospitals billing on type of bill (TOB) 83X. IHS hospitals billing on TOB 83X are paid the Ambulatory Surgery Center (ASC) payment amount. Other IHS hospitals (billing on TOB 13X) are paid the Office of Management and Budget (OMB)-approved all-inclusive rate (AIR), or the facility specific per visit amount as applicable. Deductible and coinsurance do not apply for these tests. See section A below for payment to Maryland waiver hospitals on TOB 13X. Payment to all hospitals for non-patient laboratory specimens on TOB 14X will be based on the CLFS, including CAHs and Maryland waiver hospitals.
- For claims with dates of service on or after January 1, 2015, through December 31, 2015, the Cologuard™ multi-target sDNA test (HCPCS G0464) is paid under the CLFS.

Note: For claims with dates of service October 9, 2014, thru December 31, 2014, HCPCS code G0464 is paid under local contractor pricing.

- For claims with dates of service on or after January 1, 2016, CPT code 81528 replaces G0464 *is paid under* the CLFS.

- *For claims with dates of service on or after January 19, 2021, Blood-based Biomarker test (HCPCS G0327) is paid under the CLFS*
- Flexible sigmoidoscopy (code G0104) is paid under OPPS for hospital outpatient departments and on a reasonable cost basis for CAHs; or current payment methodologies for hospitals not subject to OPPS.
- Colonoscopies (HCPCS G0105 and G0121) and barium enemas (HCPCS G0106 and G0120) are paid under OPPS for hospital outpatient departments and on a reasonable cost basis for CAHs or current payment methodologies for hospitals not subject to OPPS. Also colonoscopies may be performed in an ASC and when done in an ASC, the ASC rate applies. The ASC rate is the same for diagnostic and screening colonoscopies. The ASC rate is paid to IHS hospitals when the service is billed on TOB 83X.

The following screening codes must be paid at rates consistent with the rates of the diagnostic codes indicated. Coinsurance and deductible apply to diagnostic codes.

HCPCS Screening Code	HCPCS Diagnostic Code
G0104	45330
G0105 and G0121	45378
G0106 and G0120	74280

A. Special Payment Instructions for TOB 13X Maryland Waiver Hospitals

For hospitals in Maryland under the jurisdiction of the Health Services Cost Review Commission, screening colorectal services HCPCS G0104, G0105, G0106, 82270* (G0107*), G0120, G0121, G0328, G0464, and 81528 are paid according to the terms of the waiver, that is 94% of submitted charges minus any unmet existing deductible, co-insurance and non-covered charges. Maryland Hospitals bill TOB 13X for outpatient colorectal cancer screenings.

B. Special Payment Instructions for Non-Patient Laboratory Specimen (TOB 14X) for All Hospitals

Payment for colorectal cancer screenings (CPT 82270* (HCPCS G0107*), HCPCS G0328, and G0464 (Effective January 1, 2016, HCPCS G0464 is discontinued and replaced with CPT 81528) to a hospital for a non-patient laboratory specimen (TOB 14X), is the lesser of the actual charge, the fee schedule amount, or the National Limitation Amount (NLA), (including CAHs and Maryland Waiver hospitals). Part B deductible and coinsurance do not apply.

- ***NOTE:** For claims with dates of service prior to January 1, 2007, physicians, suppliers, and providers report HCPCS G0107. Effective January 1, 2007, HCPCS G0107 was discontinued and replaced with CPT 82270.

60.1.1 – Deductible and Coinsurance

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

There is no deductible and no coinsurance or copayment for the FOBTs (HCPCS G0107, G0328), flexible sigmoidoscopies (G0104), colonoscopies on individuals at high risk (HCPCS G0105), or colonoscopies on individuals not meeting criteria of high risk (HCPCS G0121).

Anesthesia services furnished in conjunction with and in support of a screening colonoscopy are reported with CPT code 00812 and coinsurance and deductible are waived. When a screening colonoscopy becomes a diagnostic colonoscopy, anesthesia services are reported with CPT code 00811 and with the -PT modifier; only the deductible is waived.

Coinsurance and deductible are waived for moderate sedation services (reported with G0500 or 99153) when furnished in conjunction with and in support of a screening colonoscopy service and when reported with modifier -33. When a screening colonoscopy becomes a diagnostic colonoscopy, moderate sedation services (G0500 or 99153) are reported with only the -PT modifier; only the deductible is waived.

Prior to January 1, 2007 deductible and coinsurance apply to other colorectal procedures (HCPCS G0106 and G0120). After January 1, 2007, the deductible is waived for those tests. Coinsurance applies.

Effective for claims with dates of service on and after October 9, 2014, deductible and coinsurance do not apply to the Cologuard™ multi-target sDNA screening test (HCPCS G0464). *(Note: Beginning January 1, 2016, CPT code 81528 replaced G0464).*

Effective for claims with dates of service on and after January 19, 2021, deductible and coinsurance do not apply to the Blood-based biomarker test (HCPCS G0327).

NOTE: A 25% coinsurance applies for all colorectal cancer screening colonoscopies (HCPCS G0105 and G0121) performed in ASCs and non-OPPS hospitals effective for services performed on or after January 1, 2007. The 25% coinsurance was implemented in the OPPS PRICER for OPPS hospitals effective for services performed on or after January 1, 1999.

A 25% coinsurance also applies for colorectal cancer screening sigmoidoscopies (HCPCS G0104) performed in non-OPPS hospitals effective for services performed on or after January 1, 2007. Beginning January 1, 2008, colorectal cancer screening sigmoidoscopies (HCPCS G0104) are payable in ASCs, and a 25% coinsurance applies. The 25% coinsurance for colorectal cancer screening sigmoidoscopies was implemented in the

OPPS PRICER for OPPS hospitals effective for services performed on or after January 1, 1999.

60.2 - HCPCS Codes, Frequency Requirements, and Age Requirements *(Rev. 10818; Issued: 05-20-21; Effective: 01-09-21; Implementation: 10-04-21)*

Effective for services furnished on or after January 1, 1998, the following codes are used for colorectal cancer screening services:

- CPT 82270* (HCPCS G0107*) - Colorectal cancer screening; fecal-occult blood tests, 1-3 simultaneous determinations;
- HCPCS G0104 - Colorectal cancer screening; flexible sigmoidoscopy;
- HCPCS G0105 - Colorectal cancer screening; colonoscopy on individual at high risk;

- HCPCS G0106 - Colorectal cancer screening; barium enema; as an alternative to HCPCS G0104, screening sigmoidoscopy;

- HCPCS G0120 - Colorectal cancer screening; barium enema; as an alternative to HCPCS G0105, screening colonoscopy.

Effective for services furnished on or after July 1, 2001, the following codes are added for colorectal cancer screening services:

- HCPCS G0121 - Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk.
- HCPCS G0122 - Colorectal cancer screening; barium enema (non-covered).

Effective for services furnished on or after January 1, 2004, the following code is added for colorectal cancer screening services as an alternative to CPT 82270* (HCPCS G0107*):

- HCPCS G0328 - Colorectal cancer screening; immunoassay, fecal-occult blood test, 1-3 simultaneous determinations.

Effective for services furnished on or after October 9, 2014, the following code is added for colorectal cancer screening services:

- HCPCS G0464 - Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3). Effective January 1, 2016, HCPCS G0464 is discontinued and replaced with CPT 81528.

Effective for services furnished on or after January 19, 2021, the following code is added for colorectal cancer services:

- *HCPCS G0327 - Colorectal cancer screening; blood-based biomarker Colon ca scrn;bld-bsd biomrk*

***NOTE:** For claims with dates of service prior to January 1, 2007, physicians, suppliers, and providers report HCPCS G0107. Effective January 1, 2007, HCPCS G0107 is discontinued and replaced with CPT 82270.

G0104 – Colorectal Cancer Screening; Flexible Sigmoidoscopy

Screening flexible sigmoidoscopies (HCPCS G0104) may be paid for beneficiaries who have attained age 50, when performed by a doctor of medicine or osteopathy at the frequencies noted below.

For claims with dates of service on or after January 1, 2002, A/B MACs (A) and (B) pay for screening flexible sigmoidoscopies (HCPCS G0104) for beneficiaries who have attained age 50 when these services were performed by a doctor of medicine or osteopathy, or by a physician assistant (*PA*), nurse practitioner (*NP*), or clinical nurse specialist (*CNS*) (as defined in §1861(aa)(5) of the Social Security Act (the Act) and in the Code of Federal Regulations (CFR) at 42 CFR 410.74, 410.75, and 410.76) at the frequencies noted above. For claims with dates of service prior to January 1, 2002, Medicare Administrative Contractors (MACs) pay for these services under the conditions noted only when a doctor of medicine or osteopathy performs them.

For services furnished from January 1, 1998, through June 30, 2001, inclusive:

- Once every 48 months (i.e., at least 47 months have passed following the month in which the last covered screening flexible sigmoidoscopy was performed).

For services furnished on or after July 1, 2001:

- Once every 48 months as calculated above **unless** the beneficiary does not meet the criteria for high risk of developing colorectal cancer (refer to §60.3 of this chapter) **and** he/she has had a screening colonoscopy (HCPCS G0121) within the preceding 10 years. If such a beneficiary has had a screening colonoscopy within the preceding 10 years, then he or she can have covered a screening flexible sigmoidoscopy only after at least 119 months have passed following the month that he/she received the screening colonoscopy (HCPCS G0121).

NOTE: If during the course of a screening flexible sigmoidoscopy a lesion or growth is detected which results in a biopsy or removal of the growth; the appropriate diagnostic procedure classified as a flexible sigmoidoscopy with biopsy or removal along with modifier -PT should be billed and paid rather than HCPCS G0104.

HCPCS G0105 – Colorectal Cancer; Colonoscopy on Individual at High Risk

Screening colonoscopies (HCPCS code G0105) may be paid when performed by a doctor of medicine or osteopathy at a frequency of once every 24 months for beneficiaries at high risk for developing colorectal cancer (i.e., at least 23 months have passed following the month in which the last covered HCPCS G0105 screening colonoscopy was performed). Refer to §60.3 of this chapter for the criteria to use in determining whether or not an individual is at high risk for developing colorectal cancer.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal along with modifier -PT should be billed and paid rather than HCPCS G0105.

A. Colonoscopy Cannot be Completed Because of Extenuating Circumstances

1. A/B MACs (A)

When a covered colonoscopy is attempted but cannot be completed because of extenuating circumstances, Medicare will pay for the interrupted colonoscopy as long as the coverage conditions are met for the incomplete procedure. However, the frequency standards associated with screening colonoscopies will not be applied by the Common Working File (CWF). When a covered colonoscopy is next attempted and completed, Medicare will pay for that colonoscopy according to its payment methodology for this procedure as long as coverage conditions are met, and the frequency standards will be applied by CWF. This policy is applied to both screening and diagnostic colonoscopies. When submitting a facility claim for the interrupted colonoscopy, providers are to suffix the colonoscopy.

Use of HCPCS codes with a modifier of -73 or -74 is appropriate to indicate that the procedure was interrupted. Payment for covered incomplete screening colonoscopies shall be consistent with payment methodologies currently in place for complete screening colonoscopies, including those contained in 42 CFR 419.44(b). In situations where a CAH has elected payment Method II for CAH patients, payment shall be consistent with payment methodologies currently in place as outlined in chapter 3 of this manual. As such, instruct CAHs that elect Method II payment to use modifier -53 to identify an incomplete screening colonoscopy (physician professional service(s) billed in revenue code 096X, 097X, and/or 098X). Such CAHs will also bill the technical or facility component of the interrupted colonoscopy in revenue code 075X (or other appropriate revenue code) using the -73 or -74 modifier as appropriate.

Note that Medicare would expect the provider to maintain adequate information in the patient's medical record in case it is needed by the A/B MAC (A) to document the incomplete procedure.

2. A/B MACs (B)

When a covered colonoscopy is attempted but cannot be completed because of extenuating circumstances (see chapter 12, section 30.1), Medicare will pay for the interrupted colonoscopy at a rate that is calculated using one-half the value of the inputs

for the codes. The *MPFS* database has specific values for codes 44388-53, 45378-53, G0105-53 and G0121-53. When a covered colonoscopy is next attempted and completed, Medicare will pay for that colonoscopy according to its payment methodology for this procedure as long as coverage conditions are met. This policy is applied to both screening and diagnostic colonoscopies. When submitting a claim for the interrupted colonoscopy, professional providers are to suffix the colonoscopy code with a modifier of -53 to indicate that the procedure was interrupted. When submitting a claim for the facility fee associated with this procedure, ASCs) are to suffix the colonoscopy code with modifier -73 or -74 as appropriate. Payment for covered screening colonoscopies, including that for the associated ASC facility fee when applicable, shall be consistent with payment for diagnostic colonoscopies, whether the procedure is complete or incomplete.

Note that Medicare would expect the provider to maintain adequate information in the patient's medical record in case it is needed by the A/B MAC (B) to document the incomplete procedure.

HCPCS G0106 – Colorectal Cancer Screening; Barium Enema; as an Alternative to HCPCS G0104, Screening Sigmoidoscopy

Screening barium enema examinations may be paid as an alternative to a screening sigmoidoscopy (HCPCS G0104). The same frequency parameters for screening sigmoidoscopies (see those codes above) apply.

In the case of an individual aged 50 or over, payment may be made for a screening barium enema examination (HCPCS G0106) performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed. For example, the beneficiary received a screening barium enema examination as an alternative to a screening flexible sigmoidoscopy in January 1999. Start count beginning February 1999. The beneficiary is eligible for another screening barium enema in January 2003.

The screening barium enema must be ordered in writing after a determination that the test is the appropriate screening test. Generally, it is expected that this will be a screening double contrast enema unless the individual is unable to withstand such an exam. This means that in the case of a particular individual, the attending physician must determine that the estimated screening potential for the barium enema is equal to or greater than the screening potential that has been estimated for a screening flexible sigmoidoscopy for the same individual. The screening single contrast barium enema also requires a written order from the beneficiary's attending physician in the same manner as described above for the screening double contrast barium enema examination.

CPT 82270* (HCPCS G0107*) – Colorectal Cancer Screening; FOBT, 1-3 Simultaneous Determinations

Effective for services furnished on or after January 1, 1998, screening FOBT (code 82270* (HCPCS G0107*)) may be paid for beneficiaries who have attained age 50, and at

a frequency of once every 12 months (i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed). This screening FOBT means a guaiac-based test for peroxidase activity, in which the beneficiary completes it by taking samples from two different sites of three consecutive stools. This screening requires a written order from the beneficiary's attending physician, or effective for dates of service on or after January 27, 2014, the beneficiary's attending physician assistant (*PA*), nurse practitioner (*NP*), or clinical nurse specialist (*CNS*). (The term "attending physician" is defined to mean 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.)

Effective for services furnished on or after January 1, 2004, payment may be made for an immunoassay-based FOBT (HCPCS G0328, described below) as an alternative to the guaiac-based FOBT, CPT 82270* (HCPCS G0107*). Medicare will pay for only one covered FOBT per year, either CPT 82270* (HCPCS G0107*) or HCPCS G0328, but not both.

***NOTE:** For claims with dates of service prior to January 1, 2007, physicians, suppliers, and providers report HCPCS G0107. Effective January 1, 2007, HCPCS G0107 is discontinued and replaced with CPT 82270.

HCPCS G0328 – Colorectal Cancer Screening; Immunoassay, *FOBT*, 1-3 Simultaneous Determinations

Effective for services furnished on or after January 1, 2004, screening FOBT, (HCPCS G0328) may be paid as an alternative to CPT 82270* (HCPCS G0107*) for beneficiaries who have attained age 50. Medicare will pay for a covered FOBT (either CPT 82270* (HCPCS G0107*) or HCPCS G0328, but not both) at a frequency of once every 12 months (i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed).

Screening FOBT, immunoassay, includes the use of a spatula to collect the appropriate number of samples or the use of a special brush for the collection of samples, as determined by the individual manufacturer's instructions. This screening requires a written order from the beneficiary's attending physician, or effective for claims with dates of service on or after January 27, 2014, the beneficiary's attending *PA*, *NP*, or *CNS*. (The term "attending physician" is defined to mean 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.)

HCPCS G0120 – Colorectal Cancer Screening; Barium Enema; as an Alternative to HCPCS G0105, Screening Colonoscopy

Screening barium enema examinations may be paid as an alternative to a screening colonoscopy (HCPCS G0105) examination. The same frequency parameters for screening colonoscopies (see those codes above) apply.

In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination (HCPCS G0120) performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed. For example, a beneficiary at high risk for developing colorectal cancer received a screening barium enema examination (HCPCS G0120) as an alternative to a screening colonoscopy (HCPCS G0105) in January 2000. Start counts beginning February 2000. The beneficiary is eligible for another screening barium enema examination (HCPCS G0120) in January 2002.

The screening barium enema must be ordered in writing after a determination that the test is the appropriate screening test. Generally, it is expected that this will be a screening double contrast enema unless the individual is unable to withstand such an exam. This means that in the case of a particular individual, the attending physician must determine that the estimated screening potential for the barium enema is equal to or greater than the screening potential that has been estimated for a screening colonoscopy, for the same individual. The screening single contrast barium enema also requires a written order from the beneficiary's attending physician in the same manner as described above for the screening double contrast barium enema examination.

HCPCS G0121 – Colorectal Cancer Screening; Colonoscopy on Individual Not Meeting Criteria for High Risk - Applicable On and After July 1, 2001

Effective for services furnished on or after July 1, 2001, screening colonoscopies (HCPCS G0121) performed on individuals not meeting the criteria for being at high risk for developing colorectal cancer (refer to §60.3 of this chapter) may be paid under the following conditions:

- At a frequency of once every 10 years (i.e., at least 119 months have passed following the month in which the last covered HCPCS G0121 screening colonoscopy was performed.)
- If the individual would otherwise qualify to have covered a HCPCS G0121 screening colonoscopy based on the above **but** has had a covered screening flexible sigmoidoscopy (HCPCS G0104), then he or she may have covered a HCPCS G0121 screening colonoscopy only after at least 47 months have passed following the month in which the last covered HCPCS G0104 flexible sigmoidoscopy was performed.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal along with modifier -PT should be billed and paid rather than HCPCS G0121.

HCPCS G0464 (Replaced with CPT 81528) - Multitarget sDNA Colorectal Cancer Screening Test - Cologuard™

Effective for dates of service on or after October 9, 2014, colorectal cancer screening using the Cologuard™ multi-target sDNA test (G0464/81528) is covered once every 3 years for Medicare beneficiaries that meet all of the following criteria:

- Ages 50 to 85 years,
- Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac *FOBT* 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 cancer adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

Effective for claims with dates of service on or after October 9, 2014, providers shall report *at least ONE of* the following diagnosis codes when submitting claims for the Cologuard™ multi-target sDNA test:

Z12.11 Encounter for screening for malignant neoplasm of colon, OR,

Z12.12 Encounter for screening for malignant neoplasm of rectum

NOTE: Effective January 1, 2016, HCPCS G0464 is discontinued and replaced with CPT 81528

HCPCS G0327- Colorectal Cancer Screening - Blood-based Biomarker Tests

Blood-based DNA testing detects molecular markers of altered DNA that are contained in the cells shed into the lumen of the large bowel 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 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 *FOBT* 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 cancer 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), as minimal threshold levels, based on the pivotal studies included in the FDA labeling.*

Effective for claims with dates of service on or after January 19, 2021, providers shall report at least ONE of the following diagnosis codes when submitting claims for the Blood-based Biomarker test HCPCS G0327:

Z12.11 Encounter for screening for malignant neoplasm of colon, OR,

Z12.12 Encounter for screening for malignant neoplasm of rectum

HCPCS G0122 – Colorectal Cancer Screening; Barium Enema

The code is not covered by Medicare.

60.2.1 - CWF Edits

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

Effective for dates of service January 1, 1998, and later, CWF will edit all colorectal screening claims for age and frequency standards. The CWF will also edit A/B MAC (A) claims for valid procedure codes (HCPCS G0104, G0105, G0106, CPT 82270* (HCPCS G0107*), G0120, G0121, G0122, G0328, **G0327**, and CPT 81528 ** (HCPCS G0464**). The CWF currently edits for valid HCPCS codes for A/B/MACs (B). (See §60.6 of this chapter for TOBs.)

***NOTE:** For claims with dates of service prior to January 1, 2007, physicians, suppliers, and providers report HCPCS G0107. Effective January 1, 2007, HCPCS G0107 is discontinued and replaced with CPT 82270.

****** Effective January 1, 2016, HCPCS G0464 is discontinued and replaced with CPT 81528.

60.2.2 - Ambulatory Surgical Center (ASC) Facility Fee

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

CPT code 45378, which is used to code a diagnostic colonoscopy, is on the list of procedures approved by Medicare for payment of an ambulatory surgical center facility under *section* 1833 of the Act. CPT code 45378 is currently assigned to ASC payment group 2. Code G0105, colorectal cancer; colonoscopy on individuals at high risk, was added to the ASC list effective for services furnished on or after January 1, 1998. Code G0121, colorectal cancer; colonoscopy on individual not meeting criteria for high risk, was added to the ASC list effective for services furnished on or after July 1, 2001. Codes G0105 and G0121 are assigned to ASC payment group 2. The ASC facility service is the same whether the procedure is a screening or a diagnostic colonoscopy. If during the course of the screening colonoscopy performed at an ASC, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal should be billed rather than code G0105. Effective for services performed on or after January 1, 2007, a 25% coinsurance payment will apply for the colorectal cancer services (G0105 and G0121).

60.3 - Determining High Risk for Developing Colorectal Cancer

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

A. Characteristics of the High Risk Individual

An individual at high risk for developing colorectal cancer has one or more of the following:

- A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;
- A family history of familial adenomatous polyposis;
- A family history of hereditary nonpolyposis colorectal cancer;
- A personal history of adenomatous polyps;
- A personal history of colorectal cancer; or
- Inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

B. Partial List of ICD-10-CM Codes Indicating High Risk

Listed below are some examples of diagnoses that meet the high-risk criteria for colorectal cancer. This is not an all-inclusive list. There may be more instances of conditions, which may be coded and could be considered high risk at the medical directors' discretion.

*Partial List of diagnosis codes indicating high risk: only applicable to G0105 and G0120
(high risk colorectal cancer screening)*

<i>C18.0</i>	<i>Malignant neoplasm of cecum</i>
<i>C18.2</i>	<i>Malignant neoplasm of ascending colon</i>
<i>C18.3</i>	<i>Malignant neoplasm of hepatic flexure</i>
<i>C18.4</i>	<i>Malignant neoplasm of transverse colon</i>
<i>C18.5</i>	<i>Malignant neoplasm of splenic flexure</i>
<i>C18.6</i>	<i>Malignant neoplasm of descending colon</i>
<i>C18.7</i>	<i>Malignant neoplasm of sigmoid colon</i>
<i>C18.8</i>	<i>Malignant neoplasm of overlapping sites of colon</i>
<i>C19</i>	<i>Malignant neoplasm of rectosigmoid junction</i>
<i>C20</i>	<i>Malignant neoplasm of rectum</i>
<i>C21.0</i>	<i>Malignant neoplasm of anus, unspecified</i>
<i>C21.1</i>	<i>Malignant neoplasm of anal canal</i>
<i>C21.2</i>	<i>Malignant neoplasm of cloacogenic zone</i>
<i>C21.8</i>	<i>Malignant neoplasm of overlapping sites of rectum, anus and anal canal</i>
<i>C49.A3</i>	<i>Gastrointestinal stromal tumor of small intestine</i>
<i>C49.A4</i>	<i>Gastrointestinal stromal tumor of large intestine</i>
<i>C49.A5</i>	<i>Gastrointestinal stromal tumor of rectum</i>
<i>C78.5</i>	<i>Secondary malignant neoplasm of large intestine and rectum</i>
<i>C7A.021</i>	<i>Malignant carcinoid tumor of the cecum</i>
<i>C7A.022</i>	<i>Malignant carcinoid tumor of the ascending colon</i>
<i>C7A.023</i>	<i>Malignant carcinoid tumor of the transverse colon</i>
<i>C7A.024</i>	<i>Malignant carcinoid tumor of the descending colon</i>
<i>C7A.025</i>	<i>Malignant carcinoid tumor of the sigmoid colon</i>
<i>C7A.026</i>	<i>Malignant carcinoid tumor of the rectum</i>
<i>D01.0</i>	<i>Carcinoma in situ of colon</i>
<i>D01.1</i>	<i>Carcinoma in situ of rectosigmoid junction</i>
<i>D01.2</i>	<i>Carcinoma in situ of rectum</i>
<i>D01.3</i>	<i>Carcinoma in situ of anus and anal canal</i>
<i>D12.0</i>	<i>Benign neoplasm of cecum</i>
<i>D12.2</i>	<i>Benign neoplasm of ascending colon</i>
<i>D12.3</i>	<i>Benign neoplasm of transverse colon</i>
<i>D12.4</i>	<i>Benign neoplasm of descending colon</i>
<i>D12.5</i>	<i>Benign neoplasm of sigmoid colon</i>
<i>D12.7</i>	<i>Benign neoplasm of rectosigmoid junction</i>
<i>D12.8</i>	<i>Benign neoplasm of rectum</i>
<i>D12.9</i>	<i>Benign neoplasm of anus and anal canal</i>
<i>D37.4</i>	<i>Neoplasm of uncertain behavior of colon</i>
<i>D37.5</i>	<i>Neoplasm of uncertain behavior of rectum</i>
<i>D37.9</i>	<i>Neoplasm of uncertain behavior of digestive organ, unspecified</i>
<i>D3A.021</i>	<i>Benign carcinoid tumor of the cecum</i>
<i>D3A.022</i>	<i>Benign carcinoid tumor of the ascending colon</i>
<i>D3A.023</i>	<i>Benign carcinoid tumor of the transverse colon</i>

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
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 non-infective gastroenteritis and colitis
K52.9 Non-infective 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

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

Applicable to G0464/81528: colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., kras, ndrg4 and bmp3), as well as G0327: colorectal cancer screening; blood-based biomarker - only 1 diagnosis required

Z12.12 Encounter for screening for malignant neoplasm of rectum

Z12.11 Encounter for screening for malignant neoplasm of colon

60.5 – Non-Covered Services

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

The following non-covered HCPCS codes are used to allow claims to be billed and denied for beneficiaries who need a Medicare denial for other insurance purposes for the dates of service indicated:

A. From January 1, 1998, through June 30, 2001, Inclusive

Code G0121 (colorectal cancer; colonoscopy on an individual not meeting criteria for high risk) should be used when this procedure is performed on a beneficiary who does **not** meet the criteria for high risk. This service should be denied as non-covered because it fails to meet the requirements of the benefit for these dates of service. The beneficiary is liable for payment. Note that this code is a covered service for dates of service on or after July 1, 2001.

B. On or After January 1, 1998

Code G0122 (colorectal cancer; barium enema) should be used when a screening barium enema is performed **not** as an alternative to either a screening colonoscopy (code G0105) or a screening flexible sigmoidoscopy (code G0104). This service should be denied as non-covered because it fails to meet the requirements of the benefit. The beneficiary is liable for payment.

60.6 - Billing Requirements for Claims Submitted to A/B MACs (A)

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

Follow the general bill review instructions in chapter 25. Hospitals use the ASC X12 837 institutional claim format to bill the A/B MAC (A) or the hardcopy Form CMS-1450 (UB-04). Hospitals bill revenue codes and HCPCS codes as follows:

Screening Tests/Procedures	Revenue Codes	HCPCS Codes	TOBs
FOBT	030X	82270*** (G0107***), G0328	12X, 13X, 14X**,

Screening Tests/Procedures	Revenue Codes	HCPCS Codes	TOBs
			22X, 23X, 83X, 85X
Barium enema	032X	G0106, G0120, G0122	12X, 13X, 22X, 23X, 85X****
Flexible Sigmoidoscopy	*	G0104	12X, 13X, 22X, 23X, 85X****
Colonoscopy-high risk	*	G0105, G0121	12X, 13X, 22X, 23X, 85X****
Multitarget sDNA - Cologuard™	030X	(G0464*****), 81528*****)	13X, 14X** 85X
<i>Blood-based Biomarker</i>	<i>030X</i>	<i>(G0327)</i>	<i>13X, 14X** 85X</i>

* The appropriate revenue code when reporting any other surgical procedure.

** 14X is only applicable for non-patient laboratory specimens.

*** For claims with dates of service prior to January 1, 2007, physicians, suppliers, and providers report HCPCS code G0107. Effective January 1, 2007, HCPCS G0107, was discontinued and replaced with CPT 82270.

**** CAHs that elect Method II bill revenue code 096X, 097X, and/or 098X for professional services and 075X (or other appropriate revenue code) for the technical or facility component.

***** Effective January 1, 2016, HCPCS G0464 is discontinued and replaced with CPT 81528

Special Billing Instructions for Hospital Inpatients

When these tests/procedures are provided to inpatients of a hospital or when Part A benefits have been exhausted, they are covered under this benefit. However, the provider bills on TOB 12X using the discharge date of the hospital stay to avoid editing in CWF as a result of the hospital bundling rules.

60.7 - Medicare Summary Notice (MSN) Messages

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

The following Medicare Summary Notice (MSN) messages are used (See Chapter 21 for the Spanish versions of these messages):

A. If a claim for a screening FOBT, a screening flexible sigmoidoscopy, or a barium enema is being denied because of the age of the beneficiary, use:

18.13 - This service is not covered for *people* under 50 years of age.

B. If the claim for a screening FOBT, a screening colonoscopy, a screening flexible sigmoidoscopy, or a barium enema is being denied because the time period between the same test or procedure has not passed, use:

18.14 - Service is being denied because it has not been (12, 24, 48, 120) months since your last (test/procedure) of this kind.

C. If the claim is being denied for a screening colonoscopy or a barium enema because the beneficiary is not at a high risk, use:

18.15 - Medicare covers this procedure only for *people* considered to be at a high risk for colorectal cancer.

D. If the claim is being denied because payment has already been made for a screening FOBT (CPT 82270* (HCPCS G0107*) or HCPCS G0328), flexible sigmoidoscopy (HCPCS G0104), screening colonoscopy (HCPCS G0105), or a screening barium enema (HCPCS G0106 or G0120), use:

18.16 - This service is denied because payment has already been made for a similar procedure within a set timeframe.

NOTE: MSN message 18.16 should only be used when a certain screening procedure is performed as an alternative to another screening procedure. For example: If the claims history indicates a payment has been made for HCPCS G0120 and an incoming claim is submitted for HCPCS G0105 within 24 months, the incoming claim should be denied.

E. If the claim is being denied for a non-covered screening procedure code such as HCPCS G0122, use:

16.10 - Medicare does not pay for this item or service.

If an invalid procedure code is reported, the contractor will return the claim as unprocessable to the provider under current procedures.

***NOTE:** For claims with dates of service prior to January 1, 2007, physicians, suppliers, and providers report HCPCS G0107. Effective January 1, 2007, HCPCS G0107 is discontinued and replaced with CPT 82270.

F. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* when furnished more than once in a 3-year period [at least 2 years and 11 full months (35 months total) must elapse from the date of the last screening], use:

15.19: *“We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor.”*

Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.

15.20 - The following policies NCD 210.3 were used when we made this decision

Spanish Version – “Las siguientes políticas NCD210.3 fueron utilizadas cuando se tomó esta decisión”

NOTE: Due to system requirement, the Fiscal Intermediary Standard System (FISS) has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

G. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* because the beneficiary is not between the ages of 50 and 85, use:

15.19 - *“We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor.”*

Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.

15.20 - The following policies NCD 210.3 were used when we made this decision.

Spanish Version – “Las siguientes políticas NCD 210.3 fueron utilizadas cuando se tomó esta decisión.”

NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

H. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* because the claim does not contain all of the ICD-10 diagnosis codes required, use:

15.19 - *“We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor.”*

Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.

15.20 - The following policies 210.3 were used when we made this decision

Spanish Version – “Las siguientes políticas NCD210.3 fueron utilizadas cuando se tomó esta decisión”

NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

I. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* on institutional claims when submitted on a TOB other than 13X, 14X, and 85X, use:

21.25 - This service was denied because Medicare only covers this service in certain settings.

Spanish Version: “El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones.”

60.8 - Remittance Advice Codes

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

All messages refer to ANSI X12N 835 coding.

A. If the claim for a screening FOBT, a screening flexible sigmoidoscopy, or a screening barium enema is being denied because the patient is less than 50 years of age, use:

- Claim Adjustment Reason Code (CARC) 6 “the procedure code is inconsistent with the patient’s age,” at the line level; and,
- Remittance Advice Remark Code (RARC) M82 “Service is not covered when patient is under age 50.” at the line level.

B. If the claim for a screening FOBT, a screening colonoscopy, a screening flexible sigmoidoscopy, or a screening barium enema is being denied because the time period between the test/procedure has not passed, use:

- CARC 119 “Benefit maximum for this time period *or occurrence* has been reached” at the line level.

C. If the claim is being denied for a screening colonoscopy (HCPCS G0105) or a screening barium enema (HCPCS G0120) because the patient is not at a high risk, use:

- CARC 46 “This (these) service(s) is (are) not covered” at the line level; and,
- RARC M83 “Service is not covered unless the patient is classified as a high risk.” at the line level.

D. If the service is being denied because payment has already been made for a similar procedure within the set time frame, use:

- CARC 18, “Duplicate claim/service” at the line level; and,
- RARC M86 “Service is denied because payment already made for similar procedure within a set timeframe.” at the line level.

E. If the claim is being denied for a non-covered screening procedure such as HCPCS G0122, use:

CARC 49, “These are non-covered services because this is a routine exam or screening procedure done in conjunction with a routine exam.”

F. If the claim is being denied because the code is invalid, use the following at the line level:

- CARC B18 “Payment denied because this procedure code/modifier was invalid on the date of service or claim submission.”

G. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* when furnished more than once in a 3-year period [at least 2 years and 11 full months (35 months total) must elapse from the date of the last screening], use:

- CARC 119: “Benefit maximum for this time period or occurrence has been reached.”
- RARC N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

H. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* when beneficiary is not between the ages 50-85, use:

- CARC 6: “The procedure/revenue code is inconsistent with the patient's age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N129: “Not eligible due to the patient’s age.”

Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

I. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* when the claim does not contain ICD-10 diagnosis codes Z12.12 *OR* Z12.11), use:

- CARC 167 – This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N386 – “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

J. If denying claims for Cologuard™ multi-target sDNA screening test (HCPCS G0464 - Effective January 1, 2016, HCPCS G0464 has been discontinued and replaced with CPT 81528) *or Blood-based Biomarker test (HCPCS G0327)* when claims are submitted on a TOB other than 13X, 14X, or 85X, use:

- CARC 170: “Payment is denied when performed/billed by this type of provider.
Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N95 – “This provider type/provider specialty may not bill this service.”

Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.