CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 188	**Date: December 30, 2015**
	Change Request 9115

Transmittal 3319, dated August 6, 2015, is being rescinded and replaced by Transmittal 188 to update Business Requirement 9115.04.1. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is effective for claims with dates of service on or after October 9, 2014, contractors shall recognize new HCPCS code G0464 (colorectal cancer screening; stool-based DNA and fecal occult hemoglobin) as a covered service.

EFFECTIVE DATE: October 9, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: September 8, 2015 For non-shared MAC edits; January 4, 2016 - For all shared system changes.

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	18/60/Colorectal Cancer 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 (If Applicable)
R	18/60.2.1/Common Working Files (CWF) Edits
R	18/60.4/Determining Frequency Standards
R	18/60.6/Billing Requirements for Claims Submitted to A/MACs
R	18/60.7/Medicare Summary Notices (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: 188	Date: December 30, 2015	Change Request: 9115

Transmittal 3319, dated August 6, 2015, is being rescinded and replaced by Transmittal 188 to update Business Requirement 9115.04.1. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test

EFFECTIVE DATE: October 9, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: September 8, 2015 For non-shared MAC edits; January 4, 2016 - For all shared system changes.

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. As part of the Centers for Medicare & Medicaid Services (CMS) – Food and Drug Administration (FDA) Parallel Review Pilot Program, CMS finalized an NCD for Screening for CRC Using Cologuard™ - A Multitarget Stool DNA Test.

B. Policy: After considering public comments and consulting with appropriate organizations, effective October 9, 2014, CMS determined that the evidence is sufficient to cover Cologuard™ - a multitarget stool DNA test – as a colorectal cancer screening test for asymptomatic, average risk beneficiaries, aged 50 to 85 years.

Therefore, Medicare Part B will cover the Cologuard™ test once every three years for beneficiaries who meet all of the following criteria:

- Age 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 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).

All other screening stool DNA tests not otherwise specified above remain nationally non-covered.

NOTES:

There is no coinsurance or deductible for tests paid under the Clinical Laboratory Fee Schedule (CLFS). Therefore there is no coinsurance or deductible for HCPCS code G0464 (Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)).

Only laboratories that are authorized by the manufacturer to perform the Cologuard™ test may bill for this test.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9115 - 04.1	Effective for claims with dates of service on or after October 9, 2014, contractors shall recognize new HCPCS code G0464 (Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)) as a covered service. NOTE: HCPCS G0464 is in the January 1, 2015, CLFS update with an effective date of January 1, 2015, and in the April 2015 IOCE update with an effective date of October 9, 2014. NOTE: Refer to Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 210.3 for coverage policy, and Pub. 100-04, Claims Processing Manual, Chapter 18, Section 60 for claims processing instructions. NOTE: Per the 2016 Clinical Lab Fee Schedule (CR 9465), effective December 31, 2015, HCPCS G0464 expires. Beginning January 1, 2016, CPT code 81528 is replacing G0464. Effective January 1, 2016, contractors shall recognize CPT code 81528 as a covered service when billed for the Cologuard test, and shall continue to recognize HCPCS code G0464 as a covered service for claims with prior dates of service, through December 31, 2015.	X	X			X				IOCE
9115 - 04.2	Contractors shall not apply beneficiary coinsurance and deductibles to claim lines containing HCPCS code G0464.	X	X			X				
9115 - 04.3	Effective for claims with dates of service on or after October 9, 2014, contractors shall deny line-items on claims containing HCPCS G0464					X			X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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]. NOTE: This edit shall be overridable.									
9115 - 04.3.1	When denying a line-item on claim per requirement 9115-04.3, contractors shall use the following messages: 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.	X	X							
9115 - 04.3.1.1	(Continuation of 9115-04.3.1) (Part A only) MSN 15.19: “Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD”. Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD,	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	llame al 1-800-MEDICARE (1-800-633-4227). 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." 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.									
9115 - 04.4	Effective for claims with dates of service on or after October 9, 2014, contractors shall deny line-items on claims containing HCPCS code G0464 when the beneficiary is not between ages 50-85.					X			X	
9115 - 04.4.1	When denying a line-item on claim per requirement 9115-04.4, contractors shall use the following messages: 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." (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD". Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227). 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.” 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. 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.									
9115 - 04.5	Effective for claims with dates of service on or after October 9, 2014, contractors shall deny line-items on claims containing HCPCS code G0464 when the claim does not contain all of the ICD-9 or ICD-10 diagnosis codes listed below: ICD-9: V76.41 and V76.51 ICD-10: Z12.12 and Z12.11 NOTE: This edit shall be overridable.					X	X			
9115 - 04.5.1	When denying a line-item on claim per requirement 9115.04.5, contractors shall use the following messages: 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	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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.									
9115 - 04.5.1.1	(Continuation of 4.5.1): (Part A only): MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD". Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227). 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." 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.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9115 - 04.6	Contractors shall only pay for HCPCS code G0464 claims on TOBs 13X, 14X, and 85X.					X				
9115 - 04.6.1	Contractors shall pay for HCPCS code G0464 on institutional claims in hospital outpatient departments (TOB 13X) and hospital non-patient laboratories (14X) based on the clinical laboratory fee schedule. Payment for critical access hospitals (CAHs, TOB 85X) is based on reasonable cost.					X				
9115 - 04.6.2	Contractors shall deny line-items on institutional claims for HCPCS code G0464 when submitted on a TOB other than 13X, 14X, and 85X using the following messages: 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.” MSN 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." 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. **Responsibility:** A/B MAC Part A	X								
9115 - 04.7	CWF shall calculate a next eligible date for HCPCS code G0464 for a given beneficiary. The calculation shall include all applicable factors including: • Beneficiary Part B entitlement status								X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• Beneficiary claims history • Utilization rules NOTE: The calculation for preventive services next eligible date shall parallel claims processing.									
9115 - 04.7.1	The next eligible dates shall be displayed on all CWF provider query screens (HUQA, HIQA, HIQH, ELGA, ELGH, and PRVN).	X				X			X	MBD, NGD
9115 - 04.7.2	When there is no next eligible date, the CWF provider query screens shall display this information in the date field to indicate why there is not a next eligible date								X	
9115 - 04.7.3	Any change to beneficiary master data or claims data that would result in a change to any next eligible date shall result in an update to the beneficiary's next eligible date.								X	
9115 - 04.7.4	The Multi-Carrier System Desktop Tool (MCSDT) shall display HCPCS code G0464 sessions on a separate screen and in a format equivalent to the CWF HIMR screen		X				X			
9115 - 04.8	Contractors shall apply contractor pricing to claims containing HCPCS code G0464 with dates of service October 9, 2014 through December 31, 2014.	X	X							
9115 - 04.9	Contractors shall not search for claims containing HCPCS code G0464 with dates of service on or after October 9, 2014, but contractors may adjust claims that are brought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9115 - 04.10	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	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:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Jamie Hermansen, 410-786-2064 or Jamie.Hermansen@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage) , Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims Processing Part B) , 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 (Part A 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

60 - Colorectal Cancer Screening

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

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:

- Fecal-occult blood test, immunoassay, 1-3 simultaneous determinations

Effective for claims with dates of service on or after October 9, 2014, payment may be made for colorectal cancer screening using the Cologuard™ multitarget stool DNA (sDNA) test:

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

60.1 - Payment

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

Payment is under the *Medicare Physician Fee Schedule (MPFS)* except as follows:

- *FOBTs* [*CPT* 82270* (*HCPCS* G0107*) and *HCPCS* G0328] are paid under the clinical *laboratory* fee schedule *(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)* 83*X*. IHS hospitals billing on TOB 83*X* are paid the *Ambulatory Surgery Center (ASC)* payment amount. Other IHS hospitals (billing on TOB 13*X*) 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, the Cologuard™ multitarget 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.

- 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 83*X*.

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.

Screening Code	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, *and G0464* 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*) 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 is discontinued and replaced with CPT 82270.

60.1.1 – Deductible and Coinsurance

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

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). When a screening colonoscopy becomes a diagnostic colonoscopy anesthesia code 00810 should be submitted with only the -PT modifier and only the deductible will be 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 January 1, 2015, coinsurance and deductible are waived for anesthesia services CPT 00810, Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum, when performed for screening colonoscopy services and when billed with Modifier 33.

Effective for claims with dates of service on and after October 9, 2014, deductible and coinsurance do not apply to the Cologuard™ multitarget sDNA screening test (HCPCS G0464).

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 (If Applicable)

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

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 (noncovered).

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)*

*__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, contractors 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, nurse practitioner, or clinical nurse specialist (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 C*ontractors *(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 Screening; Colonoscopy on Individual at High Risk**

Screening colonoscopies (*HCPCS* 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 contractor 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), Medicare will pay for the interrupted colonoscopy at a rate consistent with that of a flexible sigmoidoscopy as long as coverage conditions are met for the incomplete procedure. 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 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 contractor 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; Fecal-Occult Blood Test, 1-3 Simultaneous Determinations**

Effective for services furnished on or after January 1, 1998, screening FOBT (*CPT* 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 additionally, effective for dates of service on or after January 27, 2014, the beneficiary's attending physician assistant, nurse practitioner, or clinical nurse specialist. (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, Fecal-Occult Blood Test, 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, additionally, effective for claims with dates of service on or after January 27, 2014, the beneficiary's attending physician assistant, nurse practitioner, or clinical nurse specialist. (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 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 - Multitarget Stool DNA (sDNA) Colorectal Cancer Screening Test - Cologuard™

Effective for dates of service on or after October 9, 2014, colorectal cancer screening using the Cologuard™ multitarget sDNA test (G0464) 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 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).

See Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 210.3, for complete coverage requirements.

Effective for claims with dates of service on or after October 9, 2014, providers shall report the following diagnosis codes when submitting claims for the Cologuard™ multitarget sDNA test:

ICD-9: V76.41 and V76.51, or,
ICD-10: Z12.11 and Z12.12

***HCPCS* G0122 - Colorectal Cancer Screening; Barium Enema**

The code is not covered by Medicare.

60.2.1 – Common Working Files (CWF) Edits

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

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/MAC* claims for valid procedure codes (*HCPCS* G0104, G0105, G0106, *CPT* 82270* (*HCPCS* G0107*), G0120, G0121, G0122, G0328, *and G0464*). The CWF currently edits for valid HCPCS codes for *B/MACs*. (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.

60.4 - Determining Frequency Standards

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

To determine the 11-, 23-, *35-*, 47-, and 119-month periods, start counts beginning with the month after the month in which a previous test/procedure was performed.

EXAMPLE: The beneficiary received *an FOBT* in January 2000. Start count beginning with February 2000. The beneficiary is eligible to receive another blood test in January 2001 (the month after 11 full months have passed).

60.6 - Billing Requirements for Claims Submitted to *A/MACs*

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

Follow the general bill review instructions in Chapter 25. Hospitals use the ANSI X12N 837I to bill the *A/MAC* or on the hardcopy Form CMS-1450 *(UB-04).* Hospitals bill revenue codes and HCPCS codes as follows:

Screening Test*s*/Procedure*s*	**Revenue Code*s***	**HCPCS Code*s***	**TOB*s***
FOBT	030X	82270*** (G0107***), G0328	12X, 13X, 14X**, 22X, 23X, 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*	*13X, 14X**, 85X*

***** 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 G0107. Effective January 1, 2007, *HCPCS* G0107, is 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.

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 the CWF as a result of the hospital bundling rules.

60.7 – *Medicare Summary Notice (MSN) Messages*

(Rev. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

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 patients 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 patients 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™ multitarget sDNA screening test (HCPCS G0464) 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 - Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD.*
>
> *Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).*
>
> *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, 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™ multitarget sDNA screening test (HCPCS G0464) because the beneficiary is not between the ages of 50 and 85, use:

> *15.19 - Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD.*
>
> *Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).*
>
> *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 decision."

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™ multitarget sDNA screening test (HCPCS G0464) because the claim does not contain all of the ICD-9 or ICD-10 diagnosis codes required, use:

15.19 - Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD.

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

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™ multitarget sDNA screening test (HCPCS G0464) 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. 188, Issued: 12-30-2015, Effective: 10-09-2014, Implementation: 09-08-2015 for non-shared MAC edits; 01-04- 2016 - For all shared system changes.)

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 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 noncovered screening procedure such as *HCPCS* G0122, use:

- *CARC* 49, “These are noncovered 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™ multitarget sDNA screening test (HCPCS G0464) 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™ multitarget sDNA screening test (HCPCS G0464) 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™ multitarget sDNA screening test (HCPCS G0464) when the claim does not contain diagnosis codes V76.41 and V76.51 (ICD-10: Z12.12 and Z12.11 when effective), 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™ multitarget sDNA screening test (HCPCS G0464) 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.