| CMS Manual System | Department of Health & Human Services (DHHS) |
|--|--|
| Pub 100-03 Medicare National Coverage Determinations | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 12299 | Date: October 12, 2023 |
| | Change Request 13017 |

Transmittal 11865 issued February 16, 2023, is being rescinded and replaced by Transmittal 12299, dated October 12, 2023, to provide clarifications on CMS policy and related claims processing instructions for our approach to colonoscopies within the context of a complete colorectal cancer screening by revising the policy section with additional verbiage, adding Business Requirement (BR) 13017 - 04.5.3, and revising BRs 13017-04.1 and 13017 - 04.4 to 13017 - 04.10. This CR is amended to remove the requirement (and corresponding Pub. 100-04 narrative) that contractors shall return to provider/ return as un-processable certain screening colonoscopy claims that do not include the KX modifier. This correction does not make any revisions to the companion Pub. 100-02 or Pub. 100-03; all revisions are associated with Pub. 100-04. All other information remains the same.

SUBJECT: An Omnibus CR to Implement Policy Updates in the CY 2023 PFS Final Rule, Including (1) Removal of Selected NCDs (NCD 160.22 Ambulatory EEG Monitoring), and, (2) Expanding Coverage of Colorectal Cancer Screening - Full Agile Pilot CR

I. SUMMARY OF CHANGES: The purpose of this omnibus Change Request (CR) is to make contractors aware of policy updates resulting from changes specified in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Final Rule (87 FR 69404), published in the Federal Register on 11/18/2022. The policy updates include removal of one selected National Coverage Determination (NCD): Ambulatory Electroencephalographic (EEG) Monitoring (NCD 160.22). Separately, the policy updates also include policies to expand colorectal cancer screening coverage by 1) reducing the minimum age for certain CRC screening tests from 50 to 45 years and 2) expanding the regulatory definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based test returns a positive result.

EFFECTIVE DATE: January 1, 2023

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

IMPLEMENTATION DATE: November 13, 2023- For requirements subject to revision in amended CR only; February 27, 2023 - Requirements Implementation Date; April 3, 2023 - For Release Tracking Purposes Only

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 | 1/160.22/ Ambulatory EEG Monitoring |
| R | 1/210.3/ Colorectal Cancer Screening Tests |

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

Pub. 100-03 Transmittal:12299 Date: October 12, 2023 Change Request: 13017

Transmittal 11865 issued February 16, 2023, is being rescinded and replaced by Transmittal 12299, dated October 12, 2023, to provide clarifications on CMS policy and related claims processing instructions for our approach to colonoscopies within the context of a complete colorectal cancer screening by revising the policy section with additional verbiage, adding Business Requirement (BR) 13017 - 04.5.3, and revising BRs 13017-04.1 and 13017 - 04.4 to 13017 - 04.10. This CR is amended to remove the requirement (and corresponding Pub. 100-04 narrative) that contractors shall return to provider/ return as un-processable certain screening colonoscopy claims that do not include the KX modifier. This correction does not make any revisions to the companion Pub. 100-02 or Pub. 100-03; all revisions are associated with Pub. 100-04. All other information remains the same.

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I. GENERAL INFORMATION

A. Background:

NCD Removal:

National coverage policy NCD 160.22 Ambulatory EEG Monitoring was made effective on June 16, 1984. The NCD describes Ambulatory EEG monitoring is a diagnostic procedure for patients in whom a seizure diathesis is suspected but not defined by history, physical or resting EEG.

CRC Screening:

Medicare coverage for colorectal cancer (CRC) screening tests under Part B are described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Act), regulation (42 CFR 410.37), and National Coverage Determination (NCD) (Section 210.3 of the NCD Manual, Publication (Pub) 100-03). The following CRC screening tests currently include a payment and/or coverage limitation that the individual be at least 50 years of age or older:

- Screening Flexible Sigmoidoscopy Test (G0104)
- Screening Guaiac-based Fecal Occult Blood Test (gFOBT) (82270)
- Screening Immunoassay-based Fecal Occult Blood Test (iFOBT) (G0328)
- Screening The CologuardTM Multi-target Stool DNA (sDNA) Test (81528)
- Screening Barium Enema Test (G0106, G0120)
- Screening Blood-based Biomarker Tests (G0327)

In addition, and separately, Medicare policy has historically considered a colonoscopy that follows a positive result from a non-invasive stool-based CRC test (gFOBT, iFOBT or sDNA) to be a diagnostic procedure (and not a screening procedure) because the positive result from the non-invasive stool-based test represented a sign of illness. Beneficiary cost sharing is not applicable to a screening colonoscopy (G0105,

G0121) (as a specified preventive screening procedure), but is applicable to a diagnostic colonoscopy.

B. Policy: The CY 2023 PFS includes the following policy updates, effective January 1, 2023:

NCD Removal:

CMS periodically identifies and proposes to remove NCDs through public notice and comment rulemaking in the PFS that no longer contain clinically pertinent and current information or no longer reflect current medical practice.

In the CY 2023 PFS Final Rule, CMS finalized a proposal to remove NCD 160.22 EEG Monitoring. In the absence of this NCD, coverage determinations will be made by the Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Social Security Act (the Act).

CRC Screening:

The minimum age payment and/or coverage limitation for the following CRC screening tests is now reduced to 45 years of age or older:

- Screening Flexible Sigmoidoscopy Test
- Screening Guaiac-based Fecal Occult Blood Test (gFOBT)
- Screening Immunoassay-based Fecal Occult Blood Test (iFOBT)
- Screening The CologuardTM Multi-target Stool DNA (sDNA) Test
- Screening Barium Enema Test
- Screening Blood-based Biomarker Tests

Screening Colonoscopy will continue to not have a minimum age limitation. We are not modifying existing maximum age limitations (where applicable).

In addition, and separately, a positive result from a non-invasive stool-based CRC screening test no longer requires that the following colonoscopy be a diagnostic colonoscopy. CRC screening tests now include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test (gFOBT, iFOBT or sDNA) returns a positive result. We now understand both the non-invasive stool-based test and the follow-on colonoscopy to both be part of a continuum of a complete CRC screening. Beneficiary cost sharing will not apply to the non-invasive stool-based test and the follow-on screening colonoscopy in this scenario because both are specified preventive screening services. In support of this new policy, the frequency limitations for screening colonoscopy in 42 CFR 410.37(g) will not be applicable to the follow-on screening colonoscopy that follows a positive result from a stool-based test. The policy goal of not applying frequency limitations to the follow-on screening colonoscopy after a non-invasive stool-based test returns a positive result is to remove barriers and encourage the patient to proceed to the colonoscopy procedure soon after the positive result from the stool-based test.

II. BUSINESS REQUIREMENTS TABLE

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

| Number | Requirement | Re | spoi | nsibility | , | | | | | |
|---------|---------------------------------|---------|------|-----------|-----|---------------------------|-----|-----|-----|-------|
| | | A/B MAC | | | DME | Shared-System Maintainers | | | | Other |
| | | Α | В | ННН | | FISS | MCS | VMS | CWF | |
| | | | | | MAC | | | | | |
| 13017 - | NCD Removal: Effective for | X | X | | | | | | | |
| 03.1 | claims with dates of service on | | | | | | | | | |
| | or after January 1, 2023, | | | | | | | | | |
| | contractors shall be aware that | | | | | | | | | |

| Number | Requirement | Re | spoi | nsibility | , | | | | | |
|--------------|---|----|------|-----------|-----|-------|-------|-----|-----|--|
| | | Α | /B 1 | MAC | DME | Share | Other | | | |
| | | A | В | ННН | MAC | FISS | MCS | VMS | CWF | |
| | coverage determinations are made by Medicare Administrative Contractors for Ambulatory EEG Monitoring. NOTE: Also refer to Pub 100-03, NCD Manual, chapter 1, part 2, section 160.22. | | | | | | | | | |
| 13017 - 03.2 | CRC Screening: Effective for claims with dates of service on or after January 1, 2023, contractors shall be aware that NCD 210.3 Colorectal Cancer Screening Tests has been revised to reduce the minimum age limitation from 50 to 45 years for FOBT, sDNA Test and Blood-based Biomarker Tests. NOTE: Also refer to Pub 100-02, Benefit Policy Manual (BPM), chapter 15 section 280.2 Pub 100-03, NCD Manual, chapter 1, part 4, section 210.3 and Pub 100-04, Claims Processing Manual (CPM), Chapter 18 section 60. | X | X | | | | | | X | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Re | spor | ısibility | , | |
|-----------------|--|----|----------|-----------|------------|------|
| | | | A/ MA | | DME MAC | CEDI |
| | | A | В | ННН | | |
| 13017 - 03.3 | Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN | X | X | | | |

| Number | Requirement | Re | spoi | ısibility | 7 | |
|--------|---|----|------|-----------|-----|------|
| | | | | | | |
| | | | A/ | Β | DME | CEDI |
| | | | MA | AC | | |
| | | | | | MAC | |
| | | A | В | ННН | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | Connects newsletter content per the manual section referenced | | | | | |
| | above. | | | | | |

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

[&]quot;Should" denotes a recommendation.

| X-Ref | Recommendations or other supporting information: |
|-------------|--|
| Requirement | |
| Number | |

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

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

| NCD: | 210.3 |
|------------|--|
| NCD Title: | Colorectal Cancer Screening Tests |
| | www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf |
| MCD: | http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&ncdver=3&CoverageSelection=National&bc=gAAAACAAAAAA& |
| СРМ | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf |
| | The state of the s |
| ICD-10 CM | ICD-10 DX Description |
| | |
| | CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner |
| | within the confines of the policy. |
| | Partial List of Dx Codes Indicating High Risk: Only applicable to G0105 and G0120 (high risk colorectal screening) |
| | Malignant neoplasm of cecum |
| | Malignant neoplasm of ascending colon |
| | Malignant neoplasm of hepatic flexure |
| | Malignant neoplasm of transverse colon |
| | Malignant neoplasm of splenic flexure |
| | Malignant neoplasm of descending colon |
| | Malignant neoplasm of sigmoid colon |
| | Malignant neoplasm of overlapping sites of colon |
| | Malignant neoplasm of rectosigmoid junction |
| | Malignant neoplasm of rectum |
| | Malignant neoplasm of anus, unspecified |
| | Malignant neoplasm of anal canal |
| | Malignant neoplasm of cloacogenic zone |
| | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| | Gastrointestinal stromal tumor of small intestine |
| | Gastrointestinal stromal tumor of large intestine |
| | Gastrointestinal stromal tumor of rectum |
| | Secondary malignant neoplasm of large intestine and rectum |
| | Malignant carcinoid tumor of the cecum |
| | Malignant carcinoid tumor of the ascending colon |
| | Malignant carcinoid tumor of the transverse colon |
| | Malignant carcinoid tumor of the descending colon |
| | Malignant carcinoid tumor of the sigmoid colon |
| | Malignant carcinoid tumor of the rectum |
| D01.0 | Carcinoma in situ of colon |
| | Carcinoma in situ of rectosigmoid junction |
| | Carcinoma in situ of rectum |
| | Carcinoma in situ of anus and anal canal |
| | Benign neoplasm of cecum |
| | Benign neoplasm of ascending colon |
| | Benign neoplasm of transverse colon |
| | Benign neoplasm of descending colon |
| | Benign neoplasm of sigmoid colon |
| | Benign neoplasm of rectosigmoid junction |
| | Benign neoplasm of rectum |
| | Benign neoplasm of anus and anal canal |
| | Neoplasm of uncertain behavior of colon |
| | Neoplasm of uncertain behavior of rectum |
| | Neoplasm of uncertain behavior of digestive organ, unspecified |
| | Benign carcinoid tumor of the cecum |
| | Benign carcinoid tumor of the ascending colon |
| D3A.023 | Benign carcinoid tumor of the transverse colon |

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

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| ICD-10 CM | ICD-10 DX Description |
|-----------|--|
| K51.318 | Ulcerative (chronic) rectosigmoiditis with other complication |
| K51.319 | Ulcerative (chronic) rectosigmoiditis with unspecified complications |
| K51.40 | Inflammatory polyps of colon without complications |
| K51.411 | Inflammatory polyps of colon with rectal bleeding |
| | Inflammatory polyps of colon with intestinal obstruction |
| K51.413 | Inflammatory polyps of colon with fistula |
| | 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 |
| | Left sided collitis 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 collis with rectal bleeding |
| K51.812 | Other ulcerative colitis with intestinal obstruction |
| K51.813 | Other ulcerative colitis with fistula |
| K51.814 | Other ulcerative collis with abscess |
| K51.818 | Other ulcerative collis with other complication |
| K51.819 | Other ulcerative collits with unspecified complications |
| K51.90 | Ulcerative colitis, unspecified, without complications |
| K51.90 | Ulcerative colitis, unspecified with rectal bleeding |
| K51.911 | , , |
| K51.912 | Ulcerative colitis, unspecified with intestinal obstruction |
| | Ulcerative colitis, unspecified with fistula Ulcerative colitis, unspecified with abscess |
| K51.914 | Ulcerative colitis, unspecified with other complication |
| K51.916 | Ulcerative colitis, unspecified with unspecified complications |
| K51.919 | Toxic gastroenteritis and colitis |
| K52.19 | Other specified noninfective gastroenteritis and colitis |
| | |
| K52.9 | Noninfective gastroenteritis and colitis, unspecified |
| K57.20 | Diverticulitis of large intestine with perforation and abscess without bleeding |
| K57.21 | Diverticulitis of large intestine with perforation and abscess with bleeding |
| K57.30 | Diverticulosis of large intestine without perforation or abscess without bleeding |
| K57.31 | Diverticulosis of large intestine without perforation or abscess with bleeding |
| K57.32 | Diverticulitis of large intestine without perforation or abscess without bleeding |
| K57.33 | Diverticulitis of large intestine without perforation or abscess with bleeding |
| K57.40 | Diverticulitis of both small and large intestine with perforation and abscess without bleeding |
| K57.41 | Diverticulitis of both small and large intestine with perforation and abscess with bleeding |
| K57.50 | Diverticulosis of both small and large intestine without perforation or abscess without bleeding |
| K57.51 | Diverticulosis of both small and large intestine without perforation or abscess with bleeding |
| | 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 |
| | Diverticulosis of intestine, part unspecified, without perforation or abscess without bleeding |
| | 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 |

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| ICD-10 CM | ICD-10 DX Description |
|---------------|---|
| | 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 |
| | Personal history of colonic polyps |
| Applicable to | o 81528 and G0327- only 1 dx required |
| Z12.12 | Encounter for screening for malignant neoplasm of rectum |
| Z12.11 | Encounter for screening for malignant neoplasm of colon |

By 3M for CMS

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

Rule Description

| NCD: | 210.3 | | | | | | | | - | |
|---------|---|----------------|----------------------------|------------|-----------|------------|-------------|----------------|-----------|----------------|
| | | CD0445_C | PROSES CROS | 10. CD063 | 4 CD0064 | CD4047 | CD44404 | CD40000 CI | D40047) | |
| | Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | R9232, CR934 | +U, CR903 | 1, CR900 | , CR 1047 | 5, CK 11491 | , CR 12200, CI | K13017) | |
| | www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | " 01 | 10011 0010 | | | | | | | |
| | http://www.cms.gov/medicare-coverage-database/details/ncd-det | | | | overageSe | election=N | ational&bc= | gAAAACAAA | AAA& | |
| CPM | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ds/clm104c18. _l | <u>odf</u> | | | | | | |
| | | Diramana | | | | | | | | |
| | | Propose d | | | | | | Proposed | Proposed | Proposed |
| | | HCPCS/ | | | Revenue | | | MSN | CARC | RARC |
| | | CPT Part | Frequency | тов | Code | Modifier | Provider | Message | Message | Message Part |
| Part A | Rule Description Part A | A | Limitations | (Part A) | | Part A/B | | Part A | Part A | A A |
| Part A | Rule Description Part A | A | Lillitations | (Part A) | Part A | Part A/D | Specialty | ParlA | Parl A | A |
| | Effective 1/1/98, payment may be made for colorectal cancer | | | | | | | | | |
| | screening for early detection of cancer. For screening | | | | | | | | | |
| | colonoscopy services (1 type of service included in benefit) prior | | | | | | | | | |
| | t t t t t t t t t t t t t t t t t t t | G0104 | | | | | | | | |
| | | G0105 | | | | | | | | |
| | individuals not at high-risk. | G0106 | | | | | | | | |
| | I * | 82270 | | | varies by | | | | | |
| | | G0120 | | varies by | | | | varies by | varies by | |
| | | G0121 | varies by | CPT/ | HCPCS | | | rule see | rule see | varies by rule |
| Part A | | G0328 | CPT/ HCPCS | HCPCS | | N/A | N/A | below | below | see below |
| | , | | | | | | | | | |
| | | | | | | | | | | |
| | CRC Screening: | | | | | | | | | |
| | CWF/ (RC 59099/59100) & A/MACs: | | | | | | | | | |
| | Effective 1/1/2023, allow the following CRC screening tests for | | | | | | | | | |
| | ages 45 years and older: | | | | | | | | | |
| | | | | | | | | | | |
| | -Screening Fecal-Occult Blood Tests (FOBT) (HCPCS codes | | | | | | | | | |
| | G0328 and 82270) | | | | | | | | | |
| | -Screening Flexible Sigmoidoscopies (HCPCS code G0104) | | | | | | | | | |
| | -Screening Barium Enema (HCPCS codes G0106 and G0120) | | | | | | | | | |
| | CNAIR A A MAA Co. NOTE: Also refer to Dub 400 00 Devent | | | | | | | | | |
| | CWF/ & A/MACs: NOTE: Also refer to Pub 100-02, Benefit | | | | | | | | | |
| | Policy Manual (BPM), chapter 15 section 280.2 Pub 100-03, | | | | | | | | | |
| | NCD Manual, chapter 1, part 4, section 210.3 and Pub 100-04, Claims Processing Manual (CPM), Chapter 18 section 60. | | | | | | | | | |
| | | G0104 | | | | | | | | |
| | | G0104 G0106 | | | | | | | | |
| | cancer CRC screening tests that have been paid prior to April 3, | | | | | | | | | |
| | | G0120 G0328 | | | | | | 18.13 | | |
| Part A | | | N/A | N/A | N/A | N/A | N/A | 18.15 | 96 | M82 |
| . w , , | attornom. | JLL! U | . *// \ | . 4// \ | . 1// 1 | . 4// \ | 1 4// 1 | 10.10 | | 52 |

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| NCI | D: 210.3 | | | | | | | | | |
| Title | e: Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | CR9252, CR954 | 0, CR963 | 31, CR986 ² | 1, CR10473 | 3, CR11491, | , CR12280, C | R13017) | |
| ION | www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCI | D: http://www.cms.gov/medicare-coverage-database/details/ncd-det | ails.aspx?l | NCDId=281&nc | dver=3&C | CoverageS | election=Na | ational&bc= | gAAAACAAA | AAA& | |
| CP | M http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ds/clm104c18.p | <u>odf</u> | | | | | | |
| | | | | | | | | | | |
| | | Propose d HCPCS/ | | | Revenue | | | Proposed MSN | Proposed CARC | Proposed RARC |
| | | CPT Part | • | ТОВ | Code | | Provider | Message | Message | Message Part |
| Part A | Rule Description Part A | Α | Limitations | (Part A) | Part A | Part A/B | Specialty | Part A | Part A | Α |
| | CRC Screening: CWF/ & A/MACs: Effective for claims with dates of service on or after 1/1/2023, contractors shall be aware that CRC screening tests include a follow-on Screening Colonoscopy (HCPCS codes G0105 and G0121) after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. Non-invasive stool-based CRC screening Guaiac-based Fecal Occult Blood Test (gFOBT) (82270) -Screening Immunoassay-based Fecal Occult Blood Test (iFOBT) (G0328) -Screening The Cologuard™ – Multi-target Stool DNA (sDNA) Test (81528) | | | | | | | | | |
| Part A | described above. Note: For additional claims processing information, refer to Pub | 81528 82270 | no frequency limitations when the screening colonoscopy follows a positive result from a stool- based test | | | | | | | |

G0105 G0121

81528

82270 G0328

KX

Part A

Part A

to their attention.

CRC Screening:

is delivered.

By 3M for CMS

NCD: 210.3

CRC Screening: CWF & A/MACs:

A/MACs shall return to provider claims for a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based test returns a positive result when the KX modifier is not attached to the follow-on screening colonoscopy code.

Effective for claims with dates of service on and after January 1, 2023, contractors shall not apply frequency limitations to CRC screening colonoscopy (HCPCS codes G0105 and G0121) that follows a positive result from a non-invasive stool-based CRC screening test (HCPCS code G0328, 81528, or 82270) as identified by the KX modifier and described above.

A/MACs shall not search for or adjust claims for CRC screening colonoscopies, described above, that have been paid prior to

April 3, 2023. However, contractors shall adjust claims brought

A/MACs shall engage in user acceptance testing when the code

test.

CWF:

Part A

| 10.3 | | | | | | | | | |
|---|---|---|---|--|--|--|--|--|---|
| 10.3 | | | | | | | | | |
| olorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | R9252, CR954 | 10, CR963 | 31, CR9861 | I, CR10473 | 3, CR11491 | , CR12280, <mark>C</mark> l | R13017) | |
| ww.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| tp://www.cms.gov/medicare-coverage-database/details/ncd-det | ails.aspx?N | NCDId=281&nc | dver=3&C | CoverageSe | election=Na | ational&bc= | gAAAACAAA | AAA& | |
| tp://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ds/clm104c18. _l | <u>odf</u> | | | | | | |
| | | | | | | | | | |
| Rule Description Part A | Propose d HCPCS/ CPT Part A | Frequency Limitations | TOB (Part A) | Revenue Code Part A | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Part A |
| | 82270 | 1 x 12 months | 12X 13X 14X* (*only applicable for non- patient lab specimen s) 22X 23X 83X 85X | | N/A | N/A | 18.14 18.16 | 119 119 | M90 N386 |
| /MACs: Shall allow G0104 when performed by doctor of edicine/osteopathy, or by PA, NP, or CNS (as defined in 1861(aa)(5) & in CFR 42 CFR 410.74, 410.75, 410.76) at equency of 1 every 48 months (i.e., at least 47 months have assed following month in which last covered screening flexible gmoidoscopy was done) unless beneficiary does not meet iteria for high-risk (refer to §60.3) and he/she has had creening colonoscopy, G0121, within preceding 10 years. If creening colonoscopy within preceding 10 years, then he/she an have screening flexible sigmoidoscopy only after at least 19 months have passed following month that he/she received | G0104 | 1 x 48 | 13X 22X 23X 83X | *CAH Method II bill RC 096X 097X and/or 098X for PC & 075X (or other RC) for | N/A | N/Δ | 18.14 18.16 | 119 119 | M86 N386 |
| terr ont cree ffec OB- edi 227 /MA edi 186 equ asso gmo iter cree cree | native to 82270) once per 12 months; i.e., at least 11 hs have passed following month in which last covered ening FOBT was performed. Itive 1/1/04, payment may be made for immunoassay-based T, G0328, as an alternative to guaiac-based FOBT, 82270*. care will pay for only one covered FOBT per year, either 0* or G0328, but not both. ACS: Shall allow G0104 when performed by doctor of cine/osteopathy, or by PA, NP, or CNS (as defined in 1(aa)(5) & in CFR 42 CFR 410.74, 410.75, 410.76) at ency of 1 every 48 months (i.e., at least 47 months have ed following month in which last covered screening flexible bidoscopy was done) unless beneficiary does not meet it for high-risk (refer to §60.3) and he/she has had ening colonoscopy, G0121, within preceding 10 years. If ening colonoscopy within preceding 10 years, then he/she have screening flexible sigmoidoscopy only after at least months have passed following month that he/she received | native to 82270) once per 12 months; i.e., at least 11 hs have passed following month in which last covered ening FOBT was performed. tive 1/1/04, payment may be made for immunoassay-based T, G0328, as an alternative to guaiac-based FOBT, 82270*. care will pay for only one covered FOBT per year, either 0* or G0328, but not both. ACS: Shall allow G0104 when performed by doctor of cine/osteopathy, or by PA, NP, or CNS (as defined in 1(aa)(5) & in CFR 42 CFR 410.74, 410.75, 410.76) at ency of 1 every 48 months (i.e., at least 47 months have ed following month in which last covered screening flexible bidoscopy was done) unless beneficiary does not meet ia for high-risk (refer to §60.3) and he/she has had ening colonoscopy, G0121, within preceding 10 years. If ening colonoscopy within preceding 10 years, then he/she have screening flexible sigmoidoscopy only after at least months have passed following month that he/she received | native to 82270) once per 12 months; i.e., at least 11 hs have passed following month in which last covered ening FOBT was performed. tive 1/1/04, payment may be made for immunoassay-based T, G0328, as an alternative to guaiac-based FOBT, 82270*. care will pay for only one covered FOBT per year, either 0* or G0328, but not both. ACS: Shall allow G0104 when performed by doctor of cine/osteopathy, or by PA, NP, or CNS (as defined in 1(aa)(5) & in CFR 42 CFR 410.74, 410.75, 410.76) at ency of 1 every 48 months (i.e., at least 47 months have ed following month in which last covered screening flexible bidoscopy was done) unless beneficiary does not meet ia for high-risk (refer to §60.3) and he/she has had ening colonoscopy, G0121, within preceding 10 years. If ening colonoscopy within preceding 10 years, then he/she have screening flexible sigmoidoscopy only after at least months have passed following month that he/she received 1 x 48 | ACS: Shall allow FOBT 82270 or G0328 (as an applicable for non-patient lab specimen s) 22X 23X as an alternative to guaiac-based FOBT, 82270*. Care will pay for only one covered FOBT per year, either 0* or G0328, but not both. ACS: Shall allow G0104 when performed by doctor of cine/osteopathy, or by PA, NP, or CNS (as defined in 1(aa)(5) & in CFR 42 CFR 410.74, 410.75, 410.76) at ency of 1 every 48 months (i.e., at least 47 months have ed following month in which last covered screening flexible bidoscopy was done) unless beneficiary does not meet it in for high-risk (refer to §60.3) and he/she has had ening colonoscopy, G0121, within preceding 10 years. If ening colonoscopy within preceding 10 years, then he/she have screening flexible sigmoidoscopy only after at least months have passed following month that he/she received Accident of the state o | ACS: Shall allow FOBT 82270 or G0328 (as an native to 82270) once per 12 months; i.e., at least 11 hs have passed following month in which last covered ening FOBT was performed. It ive 1/1/04, payment may be made for immunoassay-based T, G0328, as an alternative to guaiac-based FOBT, 82270*. Care will pay for only one covered FOBT per year, either 0* or G0328, but not both. ACS: Shall allow G0104 when performed by doctor of cine/osteopathy, or by PA, NP, or CNS (as defined in 1(aa)(5) & in CFR 42 CFR 410.74, 410.75, 410.76) at ency of 1 every 48 months (i.e., at least 47 months have ed following month in which last covered screening flexible oidoscopy was done) unless beneficiary does not meet it in for high-risk (refer to §60.3) and he/she has had ening colonoscopy, G0121, within preceding 10 years. If ening colonoscopy within preceding 10 years, then he/she have passed following month that he/she received 10 x 48 83X RC) for | A A/MACs: Shall allow FOBT 82270 or G0328 (as an native to 82270) once per 12 months; i.e., at least 11 hs have passed following month in which last covered ening FOBT was performed. Itive 1/1/04, payment may be made for immunoassay-based T, G0328, as an alternative to guaiac-based FOBT, 82270*. Care will pay for only one covered FOBT per year, either 0* or G0328, but not both. ACs: Shall allow G0104 when performed by doctor of cine/osteopathy, or by PA, NP, or CNS (as defined in 1(aa)(5) & in CFR 42 CFR 410.74, 410.75, 410.76) at ency of 1 every 48 months (i.e., at least 47 months have ed following month in which last covered screening flexible oidoscopy was done) unless beneficiary does not meet ia for high-risk (refer to §60.3) and he/she has had ening colonoscopy, G0121, within preceding 10 years, then he/she have passed following month that he/she received **CAH** **CAH** Method II** bill RC* 096X* 096X* 097X* and/or 12X* 098X for 13X* PC & 22X* 075X (or 123X* 075X (or 12 | **A/MACs: Shall allow FOBT 82270 or G0328 (as an native to 82270) once per 12 months; i.e., at least 11 hs have passed following month in which last covered ening FOBT was performed. It ive 1/1/04, payment may be made for immunoassay-based TOBT, 82270*. It ive 1/1/04, payment may be made for immunoassay-based TOBT, 82270*. It ive 1/1/04, payment may be made for immunoassay-based TOBT, 82270*. It is an alternative to guaiac-based FOBT, 82270*. It is an alternative to guaiac-bas | & A/MACs: Shall allow FOBT 82270 or G0328 (as an native to 82270) once per 12 months; i.e., at least 11 has have passed following month in which last covered enting FOBT was performed. In this have passed following month in which last covered enting FOBT was performed. In this have passed following month in which last covered enting FOBT was performed. In this have passed following month in which last covered enting FOBT was performed. In this have passed following month in which last covered enting for non-patient lab specimen s) 22X 23X 83X 83X 83X 83X 83X 83X 83X 83X 83X 8 | & A/MACs: Shall allow FOBT 82270 or G0328 (as an native to 82270) once per 12 months; i.e., at least 11 has have passed following month in which last covered enting FOBT was performed. In this have passed following month in which last covered enting FOBT was performed. In this have passed following month in which last covered enting FOBT was performed. In this have passed following month in which last covered some forms and in the patient lab specimen so the patient lab |

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| NCI | D: 210.3 | | | | | | | | _ | |
| Titl | e: Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, 0 | R9252, CR954 | 10, CR963 | 1, CR986 | I, CR10473 | 3, CR11491 | , CR12280, C | R13017) | |
| IOI | M: www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCI | D: http://www.cms.gov/medicare-coverage-database/details/ncd-de | tails.aspx?l | NCDId=281&nc | dver=3&C | CoverageSe | election=Na | ational&bc= | gAAAACAAA | AAA& | |
| СР | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ds/clm104c18. _l | odf | | | | | | |
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| | | d | | | | | | Proposed | Proposed | Proposed |
| | | HCPCS/ | | | Revenue | | | MSN | CARC | RARC |
| | | CPT Part | | ТОВ | Code | Modifier | | Message | Message | Message Part |
| Part A | Rule Description Part A | Α | Limitations | (Part A) | | Part A/B | Specialty | Part A | Part A | Α |
| | | | | | *CAH | | | | | |
| | | | | | Method II | | | | | |
| | | | | | bill RC | | | | | |
| | | | | | 096X, | | | | | |
| | | | | | 097X, | | | | | |
| | | | | | and/or | | | | | |
| | FIGO 9 A MAA One Chall allow COACC at fragment of and account | | | 4004 | 098X for | | | | | |
| | FISS & A/MACs: Shall allow G0106 at frequency of one every | | | 12X | PC & | | | | 119 | M86 |
| | 48 months, i.e., at least 47 months have passed following | | | 13X | 075X (or | | | | 440 | NIOOC |
| | month in which last screening barium enema or screening flexible sigmoidoscopy was performed. Screening barium enema | | 1 per 48 | 22X 23X | other RC) for | | | 18.14 | 119 | N386 |
| Part A | requires written order from beneficiary's attending physician. | G0106 | months | 85X* | , | N/A | N/A | 18.16 | 97 | M86 |
| rait A | requires written order from beneficiary's attending prhysician. | 30100 | months | 00/ | 10 | IN/A | 1N//\(\tau\) | 10.10 | 31 | IVIOO |
| | | | | | *CAH | | | | | |
| | | | | | Method II | | | | | |
| | A/MACs: Shall allow screening colonoscopies, G0105 with | | | | bill RC | | | | | |
| | approved Dx when performed by doctor of medicine/osteopathy | | | | 096X | | | | | |
| | at frequency of 1 every 24 months for beneficiaries at high | | | | 097X | | | | | |
| | <u>risk</u> (i.e., at least 23 months have passed following month in | | | | and/or | | | | | |
| | which last covered G0105 screening colonoscopy was | | | 12X | 098X for | | | | | |
| | performed). | | | 13X | PC & | | | | | |
| | NOTE- There may be more instances of conditions, which may | | | 22X | 075X (or | | | | | |
| | be coded and could be considered high-risk at A/MAC | | | 23X | other | | | | 119 | M83 |
| | discretion. This edit shall be overrideable. Additional dx will be at | | | 83X | RC) for | | | 18.14 | | |
| Part A | MAC discretion. RCs 59099/59100. | G0105 | 1 x 24 months | 85X* | TC | N/A | N/A | 18.16 | 97 | M86 |

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| NCD: | : 210.3 | | | | | | | | | |
| Title | : Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, 0 | CR9252, CR954 | 0, CR963 | 31, CR986 ² | I, CR10473 | 3, CR11491 | , CR12280, <mark>C</mark> | R13017) | |
| IOM: | www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCD: | http://www.cms.gov/medicare-coverage-database/details/ncd-det | ails.aspx?l | NCDId=281&nc | dver=3&C | CoverageSe | election=Na | ational&bc= | gAAAACAAA | AAA& | |
| CPM | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ıds/clm104c18. | odf | | | | | | |
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| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | | TOB (Part A) | Revenue Code Part A | Modifier Part A/B | | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Pai A |
| Part A | A/MACs: Shall allow G0120 as alternative to G0105 with payable high-risk DX once every 24 months i.e., at least 23 months have passed following month in which last screening barium enema or last screening colonoscopy was performed, must have written order from beneficiary's attending physician. NOTE: There may be more instances of conditions, which may be coded and could be considered high-risk at medical directors' discretion. This edit shall be overrideable. Additional dx at MAC discretion. RCs 59099/59100. | G0120 | 1 x 24 months | 12X 13X 22X 23X 85X* | *CAH Method II bill RC 096X 097X and/or 098X for PC and 075X (or other RC) for | | N/A | 18.14 18.16 | 119 97 | M83 M86 |
| Part A | FISS & A/MACs: Shall allow once every 10 years i.e., at least 119 months have passed following month in which last covered G0121 screening colonoscopy was performed. If individual would otherwise qualify to have G0121 screening colonoscopy based on above (see §4180.2.D.1 and .2) but has had covered screening flexible sigmoidoscopy, G0104, then he/she may have G0121 screening colonoscopy only after at least 47 months have passed following month in which last covered G0104 flexible sigmoidoscopy was performed. NOTE: If during screening colonoscopy, a lesion/growth is detected which results in biopsy/removal of growth, appropriate dx procedure classified as colonoscopy with biopsy/removal should be billed and paid rather than G0121. | G0121 | 1 x 10 yrs for average risk patients; 1 x 2 years for high-risk patients | 12X 13X 22X 23X 83X 85X* | *CAH Method II bill RC 096X 097X and/or 098X for PC & 075X (or other RC) for | | N/A | 18.14 18.16 | 119 119 | M86 N386 |

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| Title | e: Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691 | , CR9115, C | CR9252, CR954 | 40, CR963 | 31, CR986 ² | 1, CR1047 | 3, CR11491 | , CR12280, <mark>C</mark> | R13017) | |
| ION | www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCE | D: http://www.cms.gov/medicare-coverage-database/details/ncd-de | tails.aspx?l | NCDId=281&nc | dver=3&C | CoverageS | election=N | ational&bc= | gAAAACAAA | AAA& | |
| СРІ | M http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | als/downloa | ds/clm104c18. | pdf | | | | | | |
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| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | | TOB (Part A) | | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Part A |
| | | | | | *CAH Method II | | | | | |
| | | | | | bill RC | | | | | |
| | | | | | 096X 097X | | | | | |
| | | | | | and/or 098X for | | | | | |
| | | | | 12X 13X | PC & 075X (or | | | | | |
| | FISS & A/MACs: Shall deny G0122 & 74263 as non-covered | 00400 | | 22X | other | | | | | |
| Dout A | because they fail to meet benefit requirements. Beneficiary is | G0122 | NI/A | 23X | RC) for | NI/A | NI/A | 16 10 | 40 | N420 |
| Part A | liable for payment. Codes are not covered by Medicare. | 74263 | N/A | 85X* | TC | N/A | N/A | 16.10 | 49 | N429 |

Rule Description

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|--------|---|---|--------------------------|-----------------|------------|------------|-----------------------|--------------------------------------|---------------------------------------|--------------------------------------|
| NCD | 210.3 | | | | | | | | | |
| Title | : Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | CR9252, CR954 | 10, CR963 | 31, CR9861 | 1, CR1047 | 3, CR11491 | , CR12280, C | R13017) | |
| IOM | : www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCD | http://www.cms.gov/medicare-coverage-database/details/ncd-de | tails.aspx?l | NCDId=281&nc | dver=3&C | CoverageSe | election=N | ational&bc= | gAAAACAAA | AAA& | |
| CPN | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ıls/downloa | ds/clm104c18.p | <u>odf</u> | | | | | | |
| | | | | | | | | | | |
| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | Frequency Limitations | TOB (Part A) | | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Par A |
| | FISS, A/MACs, CWF: Effective 10/9/14, shall allow Cologuard test G0464, and, Effective 1/19/21, allow Blood-Based Biomarker tests using generic G0327 unless a more specific code becomes available (G0327 effective 7/1/21) for approved dx 1 every 3 years for beneficiaries who meet all the following criteria: -Age 45 to 85 years (effective 1/1/2023, minimum age criteria reduced from 50 to 45), -Asymptomatic (no signs/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 an adenomatous polyp, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer). -Only one diagnosis- Z12.11 OR Z12.12 is required on the claim. Effective for claims with DOS on and after 1/1/16, G0464 shall be replaced with 81528. NOTE: Deductible and coinsurance are waived. CWF: NOTE: also see Pub 100-02 Benefit Policy Manual Chapter 15 Section 280.2 and Pub 100-03, NCD Manual, Chapter 1 Section 210.3. | 81528 | | | | | | 15.19 15.20 | 119 6 167 | N386 N129 N386 |
| Part A | | G0327 | 1 x 3 yrs | | N/A | N/A | N/A | 21.25 | 170 | N95 |

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|--------|--|------------------------------------|---------------|----------|-----------------|-------------|-------------|----------------------------|-----------------------------|----------------------------------|
| NCD | : 210.3 | | | | | | | | | |
| Title | : Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | R9252, CR954 | 0, CR963 | 31, CR9861 | 1, CR10473 | 3, CR11491 | , CR12280, C | R13017) | |
| IOM | : www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCD | http://www.cms.gov/medicare-coverage-database/details/ncd-det | ails.aspx?l | NCDId=281&nc | dver=3&C | CoverageSe | election=Na | ational&bc= | gAAAACAAA | AAA& | |
| CPM | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ds/clm104c18. | odf | | | | | | |
| | | | | | | | | | | |
| | | Propose d HCPCS/ CPT Part | | тов | Revenue Code | | Provider | Proposed MSN Message | Proposed CARC Message | Proposed RARC Message Part |
| Part A | Rule Description Part A | A | Limitations | | | | Specialty | _ | Part A | A A |
| | FISS, A/MACs: For colorectal cancer screening, effective 1/1/18, when anesthesia 00812 is performed in conjunction with screening colonoscopy G0105 or G0121, coinsurance and deductible will be waived for anesthesia 00812. When screening colonoscopy becomes dx colonoscopy, | 00811 | | | | | | | | |
| | anesthesia 00811 should be submitted with only -PT modifier and only deductible will be waived. | (dx) 00812 | | | | | | | | |
| Part A | | (sc) | | | | | | | | |

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|--------|--|---|--------------------------|-----------------|---------------------------|--------------------|-----------------------|--------------------------------------|---------------------------------------|---------------------------------------|
| NCD | 2: 210.3 | | | | | | | | | |
| Title | e: Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | CR9252, CR954 | 10, CR963 | 31, CR9861 | I, CR1047 | 3, CR11491 | , CR12280, <mark>C</mark> | R13017) | |
| IOM | M: www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCD | http://www.cms.gov/medicare-coverage-database/details/ncd-det | ails.aspx?l | NCDId=281&nc | dver=3&C | CoverageSe | election=N | ational&bc= | gAAAACAAA | AAA& | |
| CPI | M http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ds/clm104c18.j | <u>odf</u> | | | | | | |
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| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | | TOB (Part A) | Revenue Code Part A | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Part A |
| Part B | Rule Description Part B | Propose d HCPCS/ CPT Part B | Frequency Limitations | POS (Part B) | n/a | Modifier Part B | Provider Specialty | Proposed MSN Message Part B | Proposed CARC Message Part B | Proposed RARC Message Part B |
| Part B | Effective 1/1/98, payment may be made for colorectal cancer screening for early detection of cancer. For screening colonoscopy services (one of the services included in benefit) prior to 7/1/01, coverage was limited to high-risk individuals. Effective 7/1/01, screening colonoscopies are covered for individuals not at high-risk. CWF shall edit all colorectal screening claims for age and frequency standards. | G0104 G0105 G0106 82270 G0120 G0121 G0328 | varies by CPT/HCPCS | N/A | N/A | N/A | N/A | varies by rule see below | varies by rule see below | varies by rule see below |
| | 2023. However, contractors shall adjust claims brought to their | G0104 G0106 G0120 G0328 | | | | | | 18.13 | | |
| Part B | attention. | 82270 | N/A | N/A | N/A | N/A | N/A | 18.15 | 96 | M82 |

| , R | 12299_NCD1.XISX | | | | | | | Ruie | Descrip | uon |
|--------|---|---|--|-----------------|------------|-------------|-----------------------|--------------------------------------|---------------------------------------|--------------------------------------|
| NCD | : 210.3 | | | | | | | | | |
| Title | Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, 0 | CR9252, CR954 | 0, CR963 | 31, CR9861 | I, CR10473 | 3, CR11491 | , CR12280, <mark>C</mark> | R13017) | |
| IOM | : www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCD | http://www.cms.gov/medicare-coverage-database/details/ncd-de | tails.aspx?l | NCDId=281&nc | dver=3&C | CoverageSe | election=Na | ational&bc= | gAAAACAAA | <u> </u> | |
| CPM | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | als/downloa | ds/clm104c18.p | <u>odf</u> | | | | | | |
| | | | | | | | | | | |
| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | | TOB (Part A) | | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Par A |
| | CRC Screening: <u>CWF & B/MACs</u> : Effective for claims with dates of service on or after 1/1/2023, contractors shall be aware that CRC screening tests include a follow-on Screening Colonoscopy (HCPCS codes G0105 and G0121) after a Medicare covered non-invasive stoolbased CRC screening test returns a positive result. Non-invasive stoolbased CRC screening tests include: -Screening Guaiac-based Fecal Occult Blood Test (gFOBT) (82270) -Screening Immunoassay-based Fecal Occult Blood Test (iFOBT) (G0328) -Screening The Cologuard™ – Multi-target Stool DNA (sDNA) Test (81528) Contractors shall also be aware that frequency limitations for Screening Colonoscopy shall not apply when the screening colonoscopy follows a positive result from a stool-based test described above. | | no frequency limitations when the screening colonoscopy follows a | | | | | | | |
| Part B | Note : For additional claims processing information, refer to Pub 100-04, Medicare Claims Processing Manual, chapter 18, section 60. | 82270 | positive result from a stool-based test | | | | | | | |

| | 12205_1105 11X10X | | | | | | | | | |
|--------|--|---|--------------------------|-----------------|---------------------------|----------------------|-------------|--------------------------------------|---------------------------------------|---------------------------------------|
| | 210.3 | | | | | | | | | |
| Title: | Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | R9252, CR954 | 10, CR963 | 1, CR9861 | , CR10473 | 3, CR11491, | CR12280, CI | R13017) | |
| IOM: | www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCD: | http://www.cms.gov/medicare-coverage-database/details/ncd-det | ails.aspx?N | NCDId=281&nc | dver=3&C | overageSe | election=Na | ational&bc= | JAAAACAAA | AAA& | |
| CPM | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/download | ds/clm104c18.p | <u>odf</u> | | | | | | |
| | | | | | | | | | | |
| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | Frequency Limitations | TOB (Part A) | Revenue Code Part A | Modifier Part A/B | | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Part A |
| | · | | | , | | | | | | |
| | CRC Screening: <u>CWF & B/MACs</u> shall allow a follow-on screening colonoscopy (HCPCS code G0105 and G0121) after a Medicare covered CRC non-invasive stool-based test (HCPCS code G0328, 81528, or 82270) returns a positive result. NOTE: A -KX modifier shall be attached to a screening colonoscopy code to indicate such service was performed as a follow-on screening after a positive result from a stool-based test. | | | | | | | | | |
| | B/MACs shall return as unprocessable claims for a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based test returns a positive result, when the KX modifier is not attached to the follow-on screening colonoscopy code. CWF: Effective for claims with dates of service on and after January 1, 2023, contractors shall not apply frequency limitations to CRC screening colonoscopy (HCPCS codes G0105 and G0121) that follows a positive result from a non- | | | | | | | | | |
| | invasive stool-based CRC screening test (HCPCS code G0328, 81528, or 82270) as identified by the KX modifier and described above. B/MACs shall not search for or adjust claims for CRC screening colonoscopies, that have been paid prior to April 3, 2023. However, contractors shall adjust claims brought to their attention. | G0105 G0121 81528 82270 | | | | | | | | N822/N823 Group code |
| Part B | | G0328 | | | | KX | | | 16 | co |
| Part B | CRC Screening: <u>B/MACs</u> shall engage in user acceptance testing when the code is delivered. | | | | | | | | | |

| | 12200_1105 11X10X | | | | | | | | | |
|--------|--|---|--------------------------|-----------------|---------------------------|------------|-----------------------|--------------------------------------|---------------------------------------|---------------------------------------|
| NCD: | 210.3 | | | | | | | | | |
| Title: | Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | CR9252, CR954 | 10, CR963 | 31, CR9861 | I, CR1047 | 3, CR11491 | , CR12280, C | R13017) | |
| IOM: | www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| MCD: | http://www.cms.gov/medicare-coverage-database/details/ncd-det | tails.aspx?l | NCDId=281&nc | dver=3&0 | CoverageSe | election=N | ational&bc= | gAAAACAAA | 4AA <u>&</u> | |
| CPM | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/downloa | ds/clm104c18.p | <u>odf</u> | | | | | | |
| | | | | | | | | | | |
| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | Frequency Limitations | TOB (Part A) | Revenue Code Part A | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Part A |
| | B/MACs: Shall allow FOBT 82270 or G0328 (as an alternative | | | | | | | | | |
| | to 82270) 1 x <u>12 months</u> ; i.e., at least 11 months have passed following month in which last covered screening FOBT was | 82270 | | | | | | 18.14 | 119 | M90 |
| Part B | performed. | G0328 | 1 x 12 months | ΝΙ/Δ | N/A | N/A | N/A | 18.16 | 119 | N386 |
| Part B | B/MACs: Shall allow G0104 when performed by doctor of medicine/osteopathy, or by PA, NP, or CNS (as defined in §1861(aa)(5) & CFR 42 CFR 410.74, 410.75, 410.76) at frequency of 1 x 48 months (i.e., at least 47 months have passed following month in which last covered screening flexible sigmoidoscopy was done) unless beneficiary does not meet criteria for high-risk (refer to §60.3) and he/she has had a screening colonoscopy (HCPCS G0121) within preceding 10 years. If screening colonoscopy within preceding 10 years, then he/she can have screening flexible sigmoidoscopy only after at least 119 months have passed following month that he/she received screening colonoscopy, G0121. | G0104 | 1 x 48 months | N/A | N/A | N/A | N/A | 18.14 18.16 | 119 119 97 | M86 N386 M86 |
| | B/MACs: Shall allow G0106 at the frequency of <u>once every 48</u> <u>months</u> i.e. at least 47 months have passed following month in which last screening barium enema or screening flexible sigmoidoscopy was performed. Screening barium enema | 00400 | 1 x 48 | | | | | 18.14 | 119 119 | M86 N386 |
| Part B | requires written order from beneficiary's attending physician. | G0106 | months | N/A | N/A | N/A | N/A | 18.16 | 97 | M86 |
| | MCS (025L) & B/MACs: Shall allow G0105 with payable high risk DX 1 x 24 months i.e., at least 23 months have passed following month in which last screening barium enema or last screening colonoscopy was performed, when performed by doctor of medicine/osteopathy. MCS audit 025L NOTE- There may be additional dx considered high-risk at | | | | | | | 18.14 | 119 | M83 |
| Part B | B/MAC discretion so this edit shall be overrideable. | G0105 | 1 x 24 months | N/A | N/A | N/A | N/A | 18.16 | 97 | M86 |

| | K 12233_NCD 1.XISX | | | | | | | ITUIE | Describ | uon |
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| Т | itle: Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, 0 | CR9252, CR954 | 10, CR963 | 31, CR986 ² | I, CR10473 | 3, CR11491 | , CR12280, C | R13017) | |
| | OM: www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf | | | | | | | | | |
| М | CD: http://www.cms.gov/medicare-coverage-database/details/ncd-det | tails.aspx? | NCDId=281&nc | dver=3&C | CoverageS | election=Na | ational&bc= | gAAAACAAA | AAA& | |
| | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | | | | | | | | | |
| | | | | | | | | II. | | |
| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | | TOB (Part A) | Revenue Code Part A | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Pa |
| aitA | MCS & B/MACs: Shall allow G0120 as an alternative to G0105 | _ ^ | Lillitations | (i ait A) | TaitA | T alt A/D | Opeciaity | I alt A | I alt A | |
| | with payable high risk DX 1 every 24 months i.e., at least 23 months have passed following month in which last screening barium enema or last screening colonoscopy was performed, must have written order from beneficiary's attending physician. MCS audit 025L | | | | | | | | 140 | Moo |
| | | | | | | | | 40.44 | 119 | M83 |
| Part B | NOTE - There may be additional dx considered high risk at B/MAC discretion so this edit shall be overrideable. | G0120 | 1 x 24 months | NI/A | N/A | N/A | N/A | 18.14 18.16 | 97 | M86 |
| uit D | Emilito dicolodon do uno dal chan de evenidodese. | 00120 | T X Z T III OTILITO | 14,7 (| 14,7 (| 14,7 (| 1477 | 10.10 | 0. | Moo |
| | B/MACs: Shall allow CPT/HCPCS 1 x 10 years i.e., at least 119 months have passed following month in which last covered G0121 screening colonoscopy was performed. If individual would otherwise qualify to have covered G0121 screening colonoscopy based on above (see §4180.2.D.1 and .2) but had a covered screening flexible sigmoidoscopy, G0104, then he/she may have G0121 screening colonoscopy only after at least 47 months have passed following month in which last covered G0104 flexible sigmoidoscopy was performed. NOTE: If during screening colonoscopy, a lesion/growth is detected which results in biopsy/removal of growth, appropriate | | 1 x 10 yrs for average risk patients; 1 x 2 years for | | | | | | 119 119 | M86 N386 |
| | dx procedure classified as colonoscopy with biopsy/removal | | high risk | | | | | 18.14 | | |
| Part B | should be billed and paid rather than G0121. | G0121 | patients | N/A | N/A | N/A | N/A | 18.16 | 97 | M86 |
| | B/MACs: Shall deny G0122 and 74263 as non-covered | | | | | | | | | |
| | because they fail to meet benefit requirements. Beneficiary is | G0122 | | | | | | | | |
| Part B | liable for payment. Code is not covered by Medicare. | 74263 | N/A | N/A | N/A | N/A | N/A | 16.10 | 49 | N429 |

| _ | 12235_11001.XI3X | | | | | | | itaic | Descrip | 11011 |
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| NCD: | 210.3 | | | | | | | | | |
| Title: | Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, | CR9115, C | R9252, CR954 | 10, CR963 | 1, CR9861 | , CR10473 | 3, CR11491 | , CR12280, <mark>C</mark> | R13017) | |
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| MCD: | http://www.cms.gov/medicare-coverage-database/details/ncd-det | ails.aspx?N | ICDId=281&nc | dver=3&C | overageSe | election=Na | ational&bc= | gAAAACAAA | AAA& | |
| СРМ | http://www.cms.gov/Regulations-and-Guidance/Guidance/Manua | ls/download | ds/clm104c18.p | odf | | | | | | |
| | | | | | | | | | | |
| Part A | Rule Description Part A | Propose d HCPCS/ CPT Part A | Frequency Limitations | TOB (Part A) | Revenue Code Part A | Modifier | Provider Specialty | Proposed MSN Message Part A | Proposed CARC Message Part A | Proposed RARC Message Part A |
| | Trais Bossiphen Fully | , , | | (1 4.1171) | 1 41171 | | Оросіану | 1 41171 | | |
| | · | 81528 | | 13X 14X | | | | 15.19 15.20 | 119 6 167 | N386 N129 N386 |
| Part B | | G0327 | 1 x 3 yrs | 85X | N/A | N/A | N/A | 21.25 | 170 | N95 |
| Part B | anesthesia 00811 should be submitted with only -PT modifier and only deductible will be waived. | 00811 (dx) 00812 (sc) | | | | | | | | |
| | | | | | | | | | | |
| Date | Revision History | | | | | | | | | |

NCD: 210.3 Title: Colorectal Cancer Screening Tests (CR5127, CR8109, CR8691, CR9115, CR9252, CR9540, CR9631, CR9861, CR10473, CR11491, CR12280, CR13017) IOM: www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf MCD: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&ncdver=3&CoverageSelection=National&bc=gAAAACAAAAAA& CPM http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf Propose d **Proposed Proposed Proposed** HCPCS/ MSN CARC RARC Revenue **CPT Part** Frequency **TOB** Code Modifier **Provider** Message **Message Part** Message Part A/B | Specialty Part A Rule Description Part A Limitations (Part A) Part A Part A Part A Α

CR8691: Clarify dx code restrictions apply to high-risk colorectal screening codes.

Update CARC/RARC to comply with CORE.

Add to dx tab: "Partial List of ICD-9-CM Codes Indicating High-Risk: Only applicable to G0105 and G0120 (high risk colorectal screening)".

CR9252: Add new coverage for G0464 in Rule and dx tab.

Add contractor discretion for G0105, G0120 in rows 13/14 & 24/25.

Clarify FISS RC 59099/59100 shall be overridable per First Coast.

Clarify all editing for NCD210.3 relative to new policy for stool DNA screening being performed in CR9115.

Remove FISS, MCS from rows: 11, 20, 22, 23, 24, 25, 26. Add MCS to rows 24, 25 at their request to correspond to audit 025L. Add CWF to lines 17, 28 per MCS.

Add additional dx codes per CMS MO and Z86.010 per NGS.

Delete codes based on suggestion from JE MAC.

CR9540: Replace HCPCS G0464 with CPT 81528 as covered effective for claims with DOS on and after 1/1/16 in all related edits.

Remove redundant columns on dx tab.

Revise FISS RC31853, MCS edit 067L verbiage from 'AND' to 'OR' - ICD-10 Z12.12 OR ICD-10 Z12.11 effective 10/1/15 (ICD-9 V76.41 OR V76.51 effective 10/9/14).

CR9631: Replace 43 valid ICD-10 dx codes, 11 ICD-9 dx codes that were inadvertently removed from CR9252. FISS RC 59099, 59100.

CR9861: Add C49.A3, C49.A4, C49.A5 as 3 new approved 2017 ICD-10 dx codes effective 10/1/16. FISS RC 59099/59100, MCS 025L.

CR10473: Add statement regarding CPT 00812 from CR8874. Follow Instructions in CR 10181.

End-date CPT 00810 effective 12/31/2017.

Add CPT 00812 effective 1/1/2018.

Remove ICD-9 dx codes from spreadsheet.

CR11491: Add ICD-10 dx Z86.004 effective 10/1/19.

End-date ICD-10 dx C18.9, D12.6 effective 9/30/19.

Add CPT 74263 as non-covered for Part B omitted in error. Non-covered status per OCE. (FISS 59099, 59100)

CR12280: Add G0327 effective 7/1/2021 lines 17 &29.

Clarified CR9450 requirements "Only one diagnosis- Z12.11 OR Z12.12 is required on the claim."

Update messaging in lines 17 & 29.

CR13017: Effective 1/1/2023, reduce the minimum age requirement for specified CRC screening tests from 50 to 45 years of age.

Add a new rule that CRC screening tests include a follow-on screening colonoscopy after a positive result from a stool-based CRC screening test (the follow-on colonoscopy would no longer be diagnostic in this scenario). The follow-on screening colonoscopy is identified by the -KX modifier and frequency limitations would not apply under this rule.

160.22 Ambulatory EEG Monitoring (Retired)

(Rev. 12299; Issued:10-12-23; Effective:01-01-23; Implementation:11-13-23)

Effective January 1, 2023, the Centers for Medicare & Medicaid Services removed the national coverage determination (NCD) for Ambulatory EEG Monitoring. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act.

210.3 – Colorectal Cancer Screening Tests

(Rev. 12299; Issued:10-12-23; Effective:01-01-23; Implementation:11-13-23)

A. General

Sections 1861(s)(2)(R) and 1861(pp) of the Social Security Act (the Act) and regulations at 42 CFR 410.37 authorize Medicare coverage for screening colorectal cancer tests under Medicare Part B. The statute and regulations authorize the Secretary to add other tests and procedures (and modifications to tests and procedures for colorectal cancer screening) as the Secretary finds appropriate based on consultation with appropriate organizations.

B. Nationally Covered Indications

1. Fecal Occult Blood Tests (FOBT) (effective January 1, 2004)

Fecal occult blood tests (FOBTs) are generally divided into two types: immunoassay and guaiac types. Immunoassay (or immunochemical) fecal occult blood tests (iFOBT) use "antibodies directed against human globin epitopes. While most iFOBTs use spatulas to collect stool samples, some use a brush to collect toilet water surrounding the stool. Most iFOBTs require laboratory processing.

Guaiac fecal occult blood tests (gFOBT) use a peroxidase reaction to indicate presence of the heme portion of hemoglobin. Guaiac turns blue after oxidation by oxidants or peroxidases in the presence of an oxygen donor such as hydrogen peroxide. Most FOBTs use sticks to collect stool samples and may be developed in a physician's office or a laboratory. In 1998, Medicare began reimbursement for guaiac FOBTs, but not immunoassay type tests for colorectal cancer screening. Since the fundamental process is similar for other iFOBTs, the Centers for Medicare & Medicaid Services evaluated colorectal cancer screening using immunoassay FOBTs in general.

Effective for dates of service on and after January 1, 2004, Medicare covers one screening FOBT per annum for the early detection of colorectal cancer. This means that Medicare will cover one gFOBT or one iFOBT at a frequency of every 12 months; i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed, for beneficiaries aged 50 years and older. The beneficiary completes the existing gFOBT by taking samples from two different

sites of three consecutive stools; the beneficiary completes the iFOBT by taking the appropriate number of stool samples according to the specific manufacturer's instructions. This screening requires a written order from the beneficiary's attending physician. ("Attending physician" means a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.)

Effective January 1, 2023, the minimum age for FOBT is reduced to 45 years and older.

2. The CologuardTM – Multi-target Stool DNA (sDNA) Test (effective October 9, 2014)

Screening stool or fecal DNA (deoxyribonucleic acid, sDNA) testing detects molecular markers of altered DNA that are contained in the cells shed by colorectal cancer and pre- malignant colorectal epithelial neoplasia into the lumen of the large bowel. Through the use of selective enrichment and amplification techniques, sDNA tests are designed to detect very small amounts of DNA markers to identify colorectal cancer or pre-malignant colorectal neoplasia. The Cologuard TM – multi-target sDNA test is a proprietary in vitro diagnostic device that incorporates both sDNA and fecal immunochemical test techniques and is designed to analyze patients' stool samples for markers associated with the presence of colorectal cancer and pre-malignant colorectal neoplasia.

Effective for dates of service on or after October 9, 2014, The Cologuard[™] test is covered once every three years for Medicare beneficiaries that meet all of the following criteria:

- Age 50 to 85 years, and,
- Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test (gFOBT) or fecal immunochemical test (iFOBT)), and,
- At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

Effective January 1, 2023, the minimum age for sDNA test is reduced to 45 years and older.

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

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

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

The patient is:

- age 50-85 years, and,
- asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test), and,
- at average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

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

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

Effective January 1, 2023, the minimum age for blood-based biomarker test is reduced to 45 years and older.

C. Nationally Non-Covered Indications

All other indications for colorectal cancer screening not otherwise specified in the Act and regulations, or otherwise specified above remain nationally non-covered. Non-coverage specifically includes:

- (1) All screening sDNA tests, effective April 28, 2008, through October 8, 2014. Effective for dates of service on or after October 9, 2014, all other screening sDNA tests not otherwise specified above remain nationally non-covered.
- (2) Screening computed tomographic colonography (CTC), effective May 12, 2009.

D. Other

N/A

(This NCD was last reviewed January 2023 and includes policy updates finalized in the Calendar Year 2023 Physician Fee Schedule final rule 87 FR 69404)