CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11865	**Date: February 16, 2023**
	Change Request 13017

Transmittal 11824 issued January 27, 2023, is being rescinded and replaced by Transmittal 11865, dated, February 16, 2023, to add the Spanish version of MSN Message 18.29 to the IOM for publication 100-04. This correction does not make any revisions to the companion Pubs.100-02 or 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: 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	15/280/280.2.2- Coverage Criteria

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. 100-02	Transmittal: 11865	Date: February 16, 2023	Change Request: 13017

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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

EFFECTIVE DATE: January 1, 2023
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I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to implement policy updates specified in the CY 2023 PFS.

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 Cologuard™ – 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 Cologuard™ – 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.

Note: Contractors shall apply the instructions in CR 12656 for screening colonoscopy procedures G0105 and G0121) that become a diagnostic or therapeutic service (regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test). This CR includes updates to the Claims Processing Manual that align with the updated policies and instructions in CR 12656.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13017 - 02.1	CRC Screening: Effective for claims with dates of service on or after January 1, 2023, contractors shall be aware that the minimum age limitation for the following CRC screening tests is reduced to 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)	X	X						X	
13017 - 02.2	CRC Screening: Effective for claims with dates of service on or after January 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 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	X	X						X	

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	colonoscopy follows a positive result from a stool-based test described above. Note: For additional claims processing information, refer to Pub 100-04, Medicare Claims Processing Manual, chapter 18, section 60.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13017 - 02.3	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 Connects newsletter content per the manual section referenced above.	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): Daniel Feller, 410-786-6913 or Daniel.Feller@cms.hhs.gov

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

280.2.2- Coverage Criteria

(Rev. 11865; Issued:02-16-23; Effective: 01-01-23; Implementation:02-27-23)

The following are the coverage criteria for these screenings:

A. Screening Fecal-Occult Blood Tests (FOBT) (Codes *82270* & G0328)

Effective for services furnished on or after January 1, 2004, one screening FOBT (code *82270* **or** G0328) is covered for beneficiaries who have attained age 50, 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 done). Screening FOBT means: (1) a guaiac-based test for peroxidase activity in which the beneficiary completes it by taking samples from two different sites of three consecutive stools **or**, (2) an immunoassay (or immunochemical) test for antibody activity in which the beneficiary completes the test by taking the appropriate number of samples according to the specific manufacturer's instructions. This expanded coverage is in accordance with revised regulations at 42 CFR 410.37(a)(2) that includes " other tests determined by the Secretary through a national coverage determination." This screening requires a written order from the beneficiary's attending physician or for claims with dates of service on or after January 27, 2014, from 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.)

NOTE: For claims with dates of service prior to January 1, 2007, physicians, suppliers, and providers report HCPCS code G0107. Effective January 1, 2007, code G0107, is discontinued and replaced with CPT code 82270. For complete claims processing information refer to Pub. 100-04, Medicare Claims Processing Manual, chapter 18, section 60.

Effective January 1, 2023, the minimum age for FOBT screening tests is reduced to 45 years and older. For complete claims processing information, refer to Pub 100-04, Medicare Claims Processing Manual, chapter 18, section 60.

B. Screening Flexible Sigmoidoscopies (code G0104)

For claims with dates of service on or after January 1, 2002, A/B MACs (B) pay for screening flexible sigmoidoscopies (Code 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 Act and at 42 CFR 410.74, 410.75, and 410.76) at the frequencies noted below. For claims with dates of service prior to January 1, 2002, pay for these services under the conditions noted only when they are performed by a doctor of medicine or osteopathy.

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 done).

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 §280.2.3) **and** the beneficiary has had a screening colonoscopy (code 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 (code 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 should be billed and paid rather than code G0104.

Effective January 1, 2023, the minimum age for Screening Flexible Sigmoidoscopies is reduced to 45 years and older. For complete claims processing information, refer to Pub 100-04, Medicare Claims Processing Manual, chapter 18, section 60.

C. Screening Colonoscopies for Beneficiaries at High Risk of Developing Colorectal Cancer (Code G0105)

The A/B MAC (B) must pay for screening colonoscopies (code G0105) 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 G0105 screening colonoscopy was performed). Refer to §280.2.3 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 should be billed and paid rather than code G0105.

Effective January 1, 2023, colorectal cancer screening tests include a follow-on Screening Colonoscopy for Beneficiaries at High Risk of Developing Colorectal Cancer after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. Non-invasive stool-based colorectal cancer 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)*

The frequency limitations described for Screening Colonoscopies for Beneficiaries at High Risk of Developing Colorectal Cancer in this section shall not apply in the instance of a follow-on Screening Colonoscopy for Beneficiaries at High Risk of Developing Colorectal Cancer after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. For complete claims processing information, refer to Pub 100-04, Medicare Claims Processing Manual,

chapter 18, section 60.

D. Screening Colonoscopies Performed on Individuals Not Meeting the Criteria for Being at High-Risk for Developing Colorectal Cancer (Code G0121)

Effective for services furnished on or after July 1, 2001, screening colonoscopies (code G0121) are covered when performed under the following conditions:

1. On individuals not meeting the criteria for being at high risk for developing colorectal cancer (refer to §280.2.3);

2. At a frequency of once every 10 years (i.e., at least 119 months have passed following the month in which the last covered G0121 screening colonoscopy was performed); and

3. If the individual would otherwise qualify to have covered a G0121 screening colonoscopy based on the above (see §§280.2.2.D.1 and 2) **but** has had a covered screening flexible sigmoidoscopy (code G0104), then the individual may have a covered G0121 screening colonoscopy only after at least 47 months have passed following the month in which the last covered G0104 flexible sigmoidoscopy was performed.

NOTE: I f 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 should be billed and paid rather than code G0121.

Effective January 1, 2023, colorectal cancer screening tests include a follow-on Screening Colonoscopy Performed on Individuals Not Meeting the Criteria for Being at High-Risk for Developing Colorectal Cancer after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. Non-invasive stool-based colorectal cancer 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)*

The frequency limitations described for Colonoscopies Performed on Individuals Not Meeting the Criteria for Being at High-Risk for Developing Colorectal Cancer in this section shall not apply in the instance of a follow-on Screening Colonoscopy Performed on Individuals Not Meeting the Criteria for Being at High-Risk for Developing Colorectal Cancer after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. For complete claims processing information, refer to Pub 100-04, Medicare Claims Processing Manual, chapter 18, section 60.

E. Screening Barium Enema Examinations (codes G0106 and G0120)

Screening barium enema examinations are covered as an alternative to either a screening sigmoidoscopy (code G0104) or a screening colonoscopy (code G0105) examination. The same frequency parameters for screening sigmoidoscopies and screening colonoscopies above apply.

In the case of an individual aged 50 or over, payment may be made for a screening barium enema examination (code 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. The count starts beginning February 1999. The beneficiary is eligible for another screening barium enema in January 2003.

In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination (code 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 (code G0120) as an alternative to a screening colonoscopy (code G0105) in January 2000. The count starts beginning February 2000. The beneficiary is eligible for another screening barium enema examination (code 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 flexible sigmoidoscopy, or for a screening colonoscopy, as appropriate, 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.

Effective January 1, 2023, the minimum age for Screening Barium Enema Examinations is reduced to 45 years and older. For complete claims processing information, refer to Pub 100-04, Medicare Claims Processing Manual, chapter 18, section 60.