CMS Manual System

Pub. 100-02 Medicare Benefit Policy

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 3 **Date: DECEMBER 19, 2003**

CHANGE REQUEST 2996

I. SUMMARY OF CHANGES: Medicare coverage is being expanded for screening for early detection of colorectal cancer by adding an additional fecal occult blood test (iFOBT, immunoassay-based) that can be used as an alternative to the existing gFOBT, guaiac-based test. Medicare coverage continues to allow for one FOBT per year for beneficiaries aged 50 and over.

NEW/REVISED MATERIAL –
EFFECTIVE DATE: January 1, 2004
***IMPLEMENTATION DATE: January 5, 2004 (for coverage & HCPCS codes)**
***IMPLEMENTATION DATE: April 5, 2004 (for frequency edits 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.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15 - Table of Contents/Covered Medical and Other Health Services
R	15/280.2.1 – Covered Services and HCPCS Codes
R	15/280.2.2 – Coverage Criteria

***III. FUNDING:**

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-02	Transmittal: 3	Date: December 19, 2003	Change Request 2996

SUBJECT: Fecal-Occult Blood Tests (FOBT)

I. GENERAL INFORMATION

A. Background: Section 4104 of the Balanced Budget Act of 1997 (P.L.105-33) provides for Part B coverage of various colorectal cancer screening examinations, subject to certain frequency and payment limitations, performed on or after January 1, 1998. Coverage of these colorectal screening examinations was published in regulations at 62 FR 59079 on October 31, 1997, effective January 1, 1998. Currently, only the existing colorectal screening guaiac-based fecal-occult blood test (FOBT), G0107, is available for coverage as defined in the above regulation. In the 2003 Physician Fee Schedule final rule (67 FR 79966), the FOBT screening test regulation definition was amended, effective March 1, 2003, to provide that it could include either: (1) a guaiac-based gFOBT, or (2) other tests determined by the Secretary through a national coverage determination. Effective for dates of service January 1, 2004, and forward, Medicare will cover a new colorectal cancer screening FOBT: Code G0328, Colorectal Cancer screening; fecal-occult blood test, immunoassay, 1-3 simultaneous determinations.

B. Policy: Medicare will cover the new colorectal cancer screening FOBT G0328 beginning January 1, 2004. G0328 is payable under the clinical lab fee schedule. Medicare patients aged 50 and over can only receive one FOBT per year, either G0107 (gFOBT, or guaiac-based) or G0328 (iFOBT, or immunoassay-based). Because of this frequency limitation, the common working file (CWF) needs to build edits for this utilization. Refer to Internet-Only Manual Pub. 100-04, Medicare Claims Processing Manual, Chapter 18 §60, Preventive and Screening Services.

C. Provider Education: Intermediaries and carriers shall inform affected providers by posting either a summary or relevant portions of this document on their Web site within 2 weeks from the date of this instruction. Also, intermediaries and carriers shall publish this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that updated information about new screening FOBTs is available on their Web site.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
2996.1	A covered screening FOBT is allowed once every 12 months for beneficiaries who have attained age 50 (i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed). Medicare will allow either one covered G0107 gFOBT or one covered G0328 iFOBT, but not both, during a 12-month period.	**CWF & SSM**
2996.2	The common working file (CWF) shall build an edit for age and frequency standards for G0328. CWF must edit G0328 against G0107. That is, a beneficiary can only have either G0107 (gFOBT, guaiac-based) once every 12 months or G0328 (iFOBT, immunoassay-based) once every 12 months. CWF shall not allow both G0328 and G0107 to pay during a 12-month period for the same beneficiary**.**	**CWF & SSM**
2996.3	Standards systems shall pay for covered FOBT (G0328 and G0328QW) based on the 2004 clinical laboratory fee schedule except reasonable cost basis for Critical Access Hospitals. G0328QW identifies a laboratory registered with a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988.	**FISS & Carrier SS**
2996.4	Standard system shall pay for covered fecal occult blood tests (G0107 and G0328) billed on the following types of bills: • 13X • 83X • 85X	**FISS**
2996.5	Medicare contractors shall utilize the existing Medicare Summary (MSN) and Remittance Advice (RA) notices based on the reason for the denial. Use existing MSNs 18.13, 18.14, 18.16 with reason code 6, remark code M82, reason code 119, or reason code 18, remark code M86.	**All Medicare Contractors**
2996.6	Medicare contractors shall educate providers to bill revenue code 030X with G0328/G0328QW.	**FIs**
2996.7	Medicare contractors shall follow the general bill review instruction in IOM Pub 100-04 Chapter 18 §60.	**All Medicare Contractors**

II. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

E. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: January 1, 2004 **Implementation Date: January 5, 2004 (for coverage & HCPCS codes)** **Implementation Date: April 5, 2004 (for frequency edits only)** **Pre-Implementation Contact(s): Claudette Sikora, 410-786-5618** **Post-Implementation Contact(s): Appropriate Regional Office**	**These instructions shall be implemented within your current operating budget.**

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

Table of Contents

(Rev. 3, 12-19-03)

280.2.1 - Covered Services and HCPCS Codes

(Rev. 3, 12-19-03)

B3-4180.1

Medicare covers colorectal cancer screening test/procedures for the early detection of colorectal cancer for the HCPCS codes indicated.

A. Effective for Services Furnished On or After January 1, 1998:

G0107 - Colorectal cancer screening; fecal-Occult blood test, 1-3 simultaneous determinations;

G0104 - Colorectal cancer screening; flexible sigmoidoscopy;

G0105 - Colorectal cancer screening; colonoscopy on individual at high risk;

G0106 - Colorectal cancer screening barium enema; alternative to GO104, screening sigmoidoscopy;

G0120 - Colorectal cancer screening barium enema; alternative to GO105, screening sigmoidoscopy.

B. Effective for Services Furnished On or After July 1, 2001:

G0121 - Colorectal Cancer Screening; Colonoscopy on Individual Not Meeting Criteria for High Risk

C. *Effective for Services Furnished On or After January 1, 2004:*

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

280.2.2 - Coverage Criteria

(Rev. 3, 12-19-03)

B3-4180.2

The following are the coverage criteria for these screenings:

A. Screening Fecal-Occult Blood Tests *(FOBT)* (Codes G0107 *& G0328)*

Effective for services furnished on or after *January 1, 2004, one* screening *FOBT* (code G0107 ***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) a 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. (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.)

B. Screening Flexible Sigmoidoscopies (code G0104)

For claims with dates of service on or after January 1, 2002, carriers 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 in the Code of Federal Regulations 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.

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

The carrier 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.

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: 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 G0121.

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.