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)

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER/SECTION/SUBSECTION/TITLE</th>
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III. ATTACHMENTS:

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

*Medicare contractors only
60 - Colorectal Cancer Screening

(Rev. 52, 12-19-03)

B3-4180, B3-4180.6, A3-3660.17

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

The following services are considered colorectal cancer screening services:

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

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

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

60.1 - Payment

(Rev. 52, 12-19-03)

Payment (carrier and FI) is under the MPFS except as follows:

- Fecal occult blood tests (G0107 and G0328) are paid under the clinical diagnostic lab fee schedule except reasonable cost is paid to CAHs;
- Flexible sigmoidoscopy (code G0104) is paid under OPPS for hospital outpatient departments and on a reasonable cost basis for CAHs; or
- Colonoscopy (G0105) and barium enemas (G0106 and G0120) are paid under OPPS for hospital outpatient departments and on a reasonable costs basis for CAHs. There is no beneficiary liability for CAH services. Also colonoscopies may be done in an Ambulatory Surgical Center (ASC) and when done in an ASC the ASC rate applies. The ASC rate is the same for diagnostic and screening colonoscopies.

The following screening codes must be paid at rates consistent with the diagnostic codes indicated.

<table>
<thead>
<tr>
<th>Screening Code</th>
<th>Diagnostic Code</th>
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<tbody>
<tr>
<td>G0104</td>
<td>45330</td>
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<tr>
<td>G0105 and G0121</td>
<td>45378</td>
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<tr>
<td>G0106</td>
<td>74280</td>
</tr>
<tr>
<td>G0120</td>
<td>74280</td>
</tr>
</tbody>
</table>
Effective for services furnished on or after January 1, 1998, the following codes are used for colorectal cancer screening services:

- G0107 - Colorectal cancer screening; fecal-occult blood tests, 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; as an alternative to G0104, screening sigmoidoscopy;
- G0120 - Colorectal cancer screening; barium enema; as an alternative to G0105, screening colonoscopy.

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

- G0121 - Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk. Note that the description for this code has been revised to remove the term “noncovered.”
- G0122 - Colorectal cancer screening; barium enema (noncovered).

Effective for services furnished on or after January 1, 2004, the following code is used for colorectal cancer screening services as an alternative to G0107:

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

G0104 - Colorectal Cancer Screening; Flexible Sigmoidoscopy

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

For claims with dates of service on or after January 1, 2002, contractors pay for screening flexible sigmoidoscopies (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 above. For claims with dates of service prior to January 1, 2002, contractors pay for these services under the conditions noted only when a doctor of medicine or osteopathy performs them.

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

- Once every 48 months (i.e., at least 47 months have passed following the month in which the last covered screening flexible sigmoidoscopy was 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 §60.2 of this chapter) and he/she 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.

G0105 - Colorectal Cancer Screening; Colonoscopy on Individual at High Risk

Ref: AB-03-114

Screening colonoscopies (code G0105) may be paid when performed by a doctor of medicine or osteopathy at a frequency of once every 24 months for beneficiaries at high risk for developing colorectal cancer (i.e., at least 23 months have passed following the month in which the last covered G0105 screening colonoscopy was performed). Refer to §60.2 of this chapter for the criteria to use in determining whether or not an individual is at high risk for developing colorectal cancer.

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

A Colonoscopy Cannot be Completed Because of Extenuating Circumstances

1. FIs

When a covered colonoscopy is attempted but cannot be completed because of extenuating circumstances, Medicare will pay for the interrupted colonoscopy as long as the coverage conditions are met for the incomplete procedure. However, the frequency standards associated with screening colonoscopies will not be applied by CWF. When a covered colonoscopy is next attempted and completed, Medicare will pay for that colonoscopy according to its payment methodology for this procedure as long as coverage conditions are met, and the frequency standards will be applied by CWF. This policy is applied to both screening and diagnostic colonoscopies. When submitting a facility claim for the interrupted colonoscopy, providers are to suffix the colonoscopy HCPCS codes with a modifier of “−73” or ”−74” as appropriate to indicate that the procedure was interrupted. Payment for covered incomplete screening colonoscopies shall be consistent with payment methodologies currently in place for complete screening colonoscopies, including those contained in 42 CFR 419.44(b). In situations where a critical access hospital (CAH) has elected payment Method II for CAH patients,
payment shall be consistent with payment methodologies currently in place as outlined in Chapter 3. As such, instruct CAHs that elect Method II payment to use modifier “–53” to identify an incomplete screening colonoscopy (physician professional service(s) billed in revenue code 096X, 097X, and/or 098X). Such CAHs will also bill the technical or facility component of the interrupted colonoscopy in revenue code 075X (or other appropriate revenue code) using the “-73” or “-74” modifier as appropriate. Note that Medicare would expect the provider to maintain adequate information in the patient’s medical record in case it is needed by the contractor to document the incomplete procedure.

2. Carriers

When a covered colonoscopy is attempted but cannot be completed because of extenuating circumstances (see Chapter 12), Medicare will pay for the interrupted colonoscopy at a rate consistent with that of a flexible sigmoidoscopy as long as coverage conditions are met for the incomplete procedure. When a covered colonoscopy is next attempted and completed, Medicare will pay for that colonoscopy according to its payment methodology for this procedure as long as coverage conditions are met. This policy is applied to both screening and diagnostic colonoscopies. When submitting a claim for the interrupted colonoscopy, professional providers are to suffix the colonoscopy code with a modifier of “–53” to indicate that the procedure was interrupted. When submitting a claim for the facility fee associated with this procedure, Ambulatory Surgical Centers (ASCs) are to suffix the colonoscopy code with “–73” or “–74” as appropriate. Payment for covered screening colonoscopies, including that for the associated ASC facility fee when applicable, shall be consistent with payment for diagnostic colonoscopies, whether the procedure is complete or incomplete. Note that Medicare would expect the provider to maintain adequate information in the patient’s medical record in case it is needed by the contractor to document the incomplete procedure.

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

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

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

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

**G0107 - Colorectal Cancer Screening; Fecal-Occult Blood Test, 1-3 Simultaneous
Determinations**

*Effective for services furnished on or after January 1, 1998, screening FOBT (code
G0107) may be paid for beneficiaries who have attained age 50, and at a frequency of
once every 12 months (i.e., at least 11 months have passed following the month in which
the last covered screening FOBT was performed). This screening FOBT means a guaiac-
based test for peroxidase activity, in which the beneficiary completes it by taking samples
from two different sites of three consecutive stools. This screening requires a written
order from the beneficiary’s attending physician. (The term “attending physician” is
defined to mean a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act)
who is fully knowledgeable about the beneficiary’s medical condition, and who would be
responsible for using the results of any examination performed in the overall
management of the beneficiary’s specific medical problem.)*

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

**G0328 - Colorectal Cancer Screening; Immunoassay, Fecal-Occult Blood Test, 1-3
Simultaneous Determinations**

*Effective for services furnished on or after January 1, 2004, screening FOBT, (code
G0328) may be paid as an alternative to G0107 for beneficiaries who have attained age
50. Medicare will pay for a covered FOBT (either G0107 or G0328, but not both) at a
frequency of once every 12 months (i.e., at least 11 months have passed following the
month in which the last covered screening FOBT was performed). Screening FOBT,
immunoassay, includes the use of a spatula to collect the appropriate number of samples
or the use of a special brush for the collection of samples, as determined by the
individual manufacturer’s instructions. This screening requires a written order from the
beneficiary’s attending physician. (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.)*

**G0120 - Colorectal Cancer Screening; Barium Enema; as an Alternative to or
G0105, Screening Colonoscopy**

Screening barium enema examinations may be paid as an alternative to a screening
colonoscopy (code G0105) examination. The same frequency parameters for screening
colonoscopies (see those codes above) apply.
In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination (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. Start counts 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 colonoscopy, for the same individual. The screening single contrast barium enema also requires a written order from the beneficiary’s attending physician in the same manner as described above for the screening double contrast barium enema examination.

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

Effective for services furnished on or after July 1, 2001, screening colonoscopies (code G0121) performed on individuals not meeting the criteria for being at high risk for developing colorectal cancer (refer to §60.2 of this chapter) may be paid under the following conditions:

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

G0122 - Colorectal Cancer Screening; Barium Enema

The code is not covered by Medicare.
60.2.1 - Common Working Files (CWF) Edits

(Rev. 52, 12-19-03)

A3-3660.17.H, B3-4180.7

Effective for dates of service January 1, 1998, and later, CWF will edit all claims for colorectal screening for age and frequency standards. The CWF will also edit FI claims for valid procedure codes (G0104, G0105, G0106, G0107, G0120, G0121, G0122, and G0328) for valid bill types. The CWF currently edits for valid HCPCS codes for carriers. Effective for dates of service April 1, 2004, and later, CWF will edit all claims for colorectal cancer screening code G0328 for age and frequency standards. (See §60.6 of this chapter for bill types.)

60.6 - Billing Requirements for Claims Submitted to FIs

(Rev. 52, 12-19-03)

A3-3660.17.E and G

Follow the general bill review instructions in Chapter 25. Hospitals bill the FI on Form CMS-1450 using bill type 13X, 83X, or 85X. In addition, the hospital bills revenue codes and HCPCS codes as follows:

<table>
<thead>
<tr>
<th>Screening Test/Procedure</th>
<th>Revenue Code</th>
<th>HCPCS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occult blood test</td>
<td>030X</td>
<td>G0107, G0328</td>
</tr>
<tr>
<td>Barium enema</td>
<td>032X</td>
<td>G0106, G0120, G0122</td>
</tr>
<tr>
<td>Flexible Sigmoidoscopy</td>
<td>*</td>
<td>G0104</td>
</tr>
<tr>
<td>Colonoscopy-high risk</td>
<td>*</td>
<td>G0105, G0121</td>
</tr>
</tbody>
</table>

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

A - Special Billing Instructions for Hospital Inpatients

When these tests/procedures are provided to inpatients of a hospital, they are covered under this benefit. However, the provider bills on bill type 13X using the discharge date of the hospital stay to avoid editing in the Common Working File (CWF) as a result of the hospital bundling rules.
The following MSN messages are used (See Chapter 21 for the Spanish versions of these messages):

A - If a claim for a screening fecal-occult blood test, a screening flexible sigmoidoscopy, or a barium enema is being denied because of the age of the beneficiary, MSN message 18.13 is used.

   This service is not covered for patients under 50 years of age.

B - If the claim for a screening fecal-occult blood test, a screening colonoscopy, a screening flexible sigmoidoscopy, or a barium enema is being denied because the time period between the same test or procedure has not passed, MSN message 18.14 is used:

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

C - If the claim is being denied for a screening colonoscopy or a barium enema because the beneficiary is not at a high risk, MSN message 18.15 is used:

   Medicare covers this procedure only for patients considered to be at a high risk for colorectal cancer.

D - If the claim is being denied because payment has already been made for a screening fecal-occult blood test (G0107 or G0328), flexible sigmoidoscopy (code G0104), screening colonoscopy (code G0105), or a screening barium enema (codes G0106 or G0120), MSN message 18.16 is used:

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

NOTE: MSN message 18-16 should only be used when a certain screening procedure is performed as an alternative to another screening procedure. For example: If the claims history indicates a payment has been made for code G0120 and an incoming claim is submitted for code G0105 within 24 months, the incoming claim should be denied.

E - If the claim is being denied for a noncovered screening procedure code such as G0122, the following MSN message 16.10 is used:

   Medicare does not pay for this item or service.

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