Medicare
Intermediary Manual
Part 3 - Claims Process

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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CHANGE REQUEST 1552

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
3660.17 – 3660.17 (Cont.)	6-344.6G–6-344.6L (6 pp.)	6-344.6G–6.344.6L (6 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: July 1, 2001*
IMPLEMENTATION DATE: July 1, 2001

Section 3660.17, Colorectal Screening, expands coverage of screening colonoscopies for Medicare beneficiaries not at high risk for developing colorectal cancer.

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previous published in the manual and is only being reprinted.

Effective October 1, 1994, all facilities providing screening and diagnostic mammography services (except VA facilities) must have a certificate issued by FDA to continue to operate. On September 30, 1994, HCFA stopped conducting surveys of screening mammography facilities. The responsibility for collecting certificate fees and surveying mammography facilities (screening and diagnostic) was transferred to the FDA, Center for Devices and Radiological Health.

A. General.--Pay diagnostic and screening mammography services for claims submitted by your providers only if the provider furnishing the service has been issued an MQSA certificate by the FDA. You are responsible for determining prior to payment that the provider has a certificate. In addition, you are also responsible for ensuring that payment is not made in situations where a provider's certificate has expired, or it has been suspended or revoked or the provider has been issued a written notification by the FDA stating that it must cease conducting mammography examinations because it is not in compliance with certain critical FDA certification requirements.

B. Under Arrangements.--When a provider obtains mammography services for its patients under arrangements with another facility, the provider must ensure that the facility performing the services has been issued a MQSA certificate from the FDA.

C. Denied Services.--If the provider that performed the mammography service has not been issued a certificate by the FDA or the certificate is suspended or revoked, deny the claim utilizing the denial language in §3660.10.H, relating to certified facilities.

D. Notification of Certified Facilities.--The FDA will provide HCFA with a listing of all providers that have been issued certificates to perform mammography services and HCFA will notify you accordingly. You will also be notified of situations where a provider's certificate has expired, or has been suspended or revoked. The information provided to you will include the providers name, address, six position certification number, and effective/termination dates.

3660.17 Colorectal Screening.--Section 4104 of the Balanced Budget Act of 1997 (P.L. 105-33) provides for Part B coverage of various colorectal examinations performed on or after January 1, 1998. Medicare will cover the following tests/procedures furnished for the purpose of early detection of colorectal cancer. Coverage of colorectal cancer screening tests includes the following procedures furnished to an individual for the early detection of colorectal cancer.

- o Screening fecal-occult blood test;
- o Screening flexible sigmoidoscopy;
- o Screening colonoscopy, for high risk individuals; and
- o Screening barium enema as an alternative to screening flexible sigmoidoscopy or screening colonoscopy.

A. HCPCS Coding.--The following new HCPCS codes have been established for these services:

- o G0107--Colorectal cancer screening; fecal-occult blood test, 1-3 simultaneous determinations;
- o G0104--Colorectal cancer screening; flexible sigmoidoscopy;
- o G0105--Colorectal cancer screening; colonoscopy on individual at high risk;
- o G0106--Colorectal cancer screening; barium enema; as an alternative to G0104, screening sigmoidoscopy;
- o G0120--Colorectal cancer screening; barium enema; as an alternative to G0105, screening colonoscopy;
- o G0121--Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk;

NOTE: Effective for services furnished on or after July 1, 2001, the description of this code (G0121) has been revised to remove the term “non-covered”

- o G0122--Colorectal cancer screening; barium enema (non-covered).

B. Coverage.--The following are the coverage criteria for these new screenings:

o Screening fecal-occult blood tests (code G0107) are covered at a frequency of 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 fecal-occult blood test was done). Screening fecal-occult blood test 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" 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.)

o Screening flexible sigmoidoscopies (code G0104) are covered at a frequency of once every 48 months for beneficiaries who have attained age 50 (i.e., at least 47 months have passed following the month in which the last covered screening flexible sigmoidoscopy was done). 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. This screening must be performed by a doctor of medicine or osteopathy. See below for criteria for claims furnished on or after July 1, 2001.

o Screening colonoscopies (code G0105) are covered at a frequency of once every 24 months for beneficiaries at high risk for colorectal cancer (i.e., at least 23 months have passed following the month in which the last covered screening colonoscopy was done). High risk for colorectoral cancer means an individual with one or more of the following:

-- A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyposis;

-- A family history of familial adenomatous polyposis;

-- A family history of hereditary nonpolyposis colorectal cancer;

-- A personal history of adenomatous polyps;

-- A personal history of colorectal cancer; or

-- Inflammatory bowel disease, including Crohn's Disease and ulcerative colitis.

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. This screening must be performed by a doctor of medicine or osteopathy.

Section 103 of the Benefits and Improvement and Protection Act for 2000 provides for coverage of screening colonoscopies performed on or after July 1, 2001, for individuals not at high risk for colorectal cancer. Screening colonoscopies (G0121) are covered at a frequency of once every 10 years for beneficiaries not at high risk for colorectal cancer (i.e., at least 119 months have passed following the month in which the last covered screening colonoscopy was done), or in the case of such individuals who may have had a covered screening flexible sigmoidoscopy, they have to wait another 4 years before they qualify for a covered screening colonoscopy (i.e., at least 47 months will have passed following the month in which the last covered screening flexible sigmoidoscopy was performed). In addition, this provision also amended the frequency of coverage for screening flexible sigmoidoscopies (code G0104). Screening flexible sigmoidoscopies are covered once every 48 months unless the beneficiary is not at high risk for colorectal cancer and has had a screening

colonoscopy (code G0121) within the last 10 years. A beneficiary not at high risk is not covered for a screening flexible sigmoidoscopy until 119 months after the month he/she received the screening colonoscopy.

o Screening barium enema examinations (codes G0106 and G0120) are covered as an alternative to either a screening sigmoidoscopy (code G0104) or a screening colonoscopy (code G0105) examination. The same frequency parameters specified in the law for screening sigmoidoscopy and screening colonoscopy apply.

-- In the case of an individual age 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.

-- In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination 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.

-- The screening barium enema must be ordered in writing after a determination that the test is the appropriate screening test. 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 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.

Listed below are some examples of diagnoses that meet the high risk criteria for colorectal cancer. This is not an all inclusive list. There may be more conditions which may be coded and at the medical directors' discretion.

ICD-9-CM Codes

Personal History:

V10.05 Personal history of malignant neoplasm of large intestine
V10.06 Personal history of malignant of rectum, rectosigmoid junction, and anus

Chronic Digestive Disease Condition

555.0 Regional enteritis of small intestine
555.1 Regional enteritis of large intestine
555.2 Regional enteritis of small intestine with large intestine
555.9 Regional enteritis of unspecified site
556.0 Ulcerative (chronic) enterocolitis
556.1 Ulcerative (chronic) ileocolitis
556.2 Ulcerative (chronic) proctitis
556.3 Ulcerative (chronic) proctosigmoiditis
556.8 Other ulcerative colitis
556.9 Ulcerative colitis, unspecified (non-specific PDX on the MCE)

Inflammatory Bowel

558.2 Toxic gastroenteritis and colitis
558.9 Other and unspecified non-infectious gastroenteritis and colitis

C. Non-covered Services.--Two non-covered HCPCS codes have been created to assist in editing for the following:

o Code G0121 (colorectal cancer screening; colonoscopy on an individual not meeting criteria for high risk) should be used when this procedure is performed on a beneficiary who does NOT meet the criteria for high risk. This service should be denied as a non-covered Medicare service. The beneficiary is liable for payment.

NOTE: This code is a covered service for dates of service on or after July 1, 2001.

o Code G0122 (colorectal cancer screening; barium enema) should be used when a screening barium enema is performed NOT as a alternative to either a screening colonoscopy (code G0105) or a screening flexible sigmoidoscopy (code G0104). This service should be denied as a non-covered Medicare service. The beneficiary is liable for payment.

Reporting of these non-covered codes will also allow claims to be billed and denied for beneficiaries who need a Medicare denial for other insurance purposes.

D. Determining Frequency Standards.--To determine the 11, 23, 47, and 119 month periods, start your count beginning with the month after the month in which a previous test/procedure was performed.

EXAMPLE: The beneficiary received a fecal-occult blood test in January 1998. Start your count beginning with February 1998. The beneficiary is eligible to receive another blood test in January 1999 (the month after 11 full months have passed).

E. Billing Requirements for Intermediaries.--Follow the general bill review instructions in §3604 of the Medicare Intermediary Manual, Part 3. Hospitals bill you on Form HCFA-1450 using bill type 13x, 83x, or 85x. In addition, the hospital bills revenue codes and HCPCS codes as follows:

Screening Test/Procedure	Rev Code	HCPCS Code
occult blood test	30X	G0107
barium enema	32X	G0106, G0120, G0122
flexible sigmoidoscopy	*	G0104
colonoscopy-high risk	*	G0105, G0121

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

F. Payment Requirements for Intermediaries.--Payment with the exception of fecal-occult blood test will be as follows:

o Payment for screening flexible sigmoidoscopy (code G0104) will be under outpatient prospective payment system (OPPS) for hospital outpatient departments and on a reasonable cost basis for critical access hospitals (CAHs); and

o Payment for screening colonoscopy (code G0105), and payment for screening barium enema (codes G0106 or G0120) will be under OPPS for hospital outpatient departments and on a reasonable cost basis for CAHs. There is no beneficiary liability for CAHs.

For screening fecal-occult blood test (code G0107) payment is under the clinical diagnostic laboratory fee schedule using payment amount associated with G0107; and on a reasonable cost basis for CAHs.

G. 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 you 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.

H. Common Working Files (CWF) Edits.--Effective for dates of service January 1, 1998, and later, CWF will edit all claims for colorectal screening for age and frequency standards. CWF will also edit fiscal intermediary claims for valid procedure codes (G0104, G0105, G0106, G0107, G0120, G0121, and G0122) and for valid bill types. CWF currently edits for valid HCPCS codes for carriers.

I. Medicare Summary Notices (MSN) and Explanation of Your Medicare Benefits (EOMB) Messages.--Intermediaries that have not yet converted to MSN should utilize the following EOMB messages. Intermediaries that have converted to MSN should utilize the following MSN messages.

If the 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 beneficiaries, state on the MSN or EOMB the following message:

“This service is not covered for beneficiaries under 50 years of age” (MSN Message 18-13, EOMB Message 18-22).

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, state on the MSN or EOMB the following message:

“Service is being denied because it has not been (12, 24, 48, 120) months since your last (test/procedure) of this kind” (MSN Message 18-14, EOMB Message 18-23).

If the claim is being denied for a screening colonoscopy or a barium enema because the beneficiary is not at a high risk, state on the MSN or EOMB the following message:

“Medicare only covers this procedure for beneficiaries considered to be at a high risk for colorectal cancer” (MSN Message 18-15, EOMB Message 18-24).

If the claim is being denied because payment has already been made for a screening flexible sigmoidoscopy (code G0104), screening colonoscopy (code G0105), or a screening barium enema (codes G0106 and G0120), use the following message:

“This item or service was denied because payment has already been made for a similar procedure within a set timeframe.” (MSN Message 18-16, EOMB Message 18-25).

NOTE: The above message (MSN 18-16 and EOMB 18-25) 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.

If an invalid procedure code is reported return the claim to the provider as outlined in 3656.5C1.

If the claim is being denied for non-covered screening procedure codes G0121 or G0122, use the following message:

"Medicare does not pay for this item or service." (MSN Message 16.10, EOMB Message 16.17).

J. Remittance Advice Notices.--If the claim for a screening fecal-occult blood test, a screening flexible sigmoidoscopy, or a barium enema is being denied because the patient is under 50 years of age, use existing American National Standard Institute (ANSI) X-12-835 claim adjustment reason code 6 "The procedure code is inconsistent with the patient's age," at line level along with line level remark code M82 "Service is not covered when beneficiary is under age 50."

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 test/procedure has not passed, use existing ANSI X12-835 claim adjustment reason code 119 "Benefit maximum for this time period has been reached" at the line level.

If the claim is being denied for a screening colonoscopy or a barium enema because the beneficiary is not at a high risk, use existing ANSI X-12-835 claim adjustment reason code 46 "This procedure is not covered" along with line level remark code M83 "Service is not covered unless the beneficiary is classified as a high risk."

If the service is being denied because payment has already been made for a similar procedure within the set timeframe, use existing ANSI X-12-835 claim adjustment reason code 18, "Duplicate claim/service" along with line level remark code M86 "This service is denied because payment has already been made for a similar procedure within a set timeframe."

If the claim is being denied because the procedure code is invalid, use existing ANSI X-12-835 claim adjustment reason code B18 "Claim/Service denied because this procedure code/modifier was invalid on the date of service or claim submission" at the line level.

If the claim is being denied for non-covered screening procedure codes G0121 or G0122, use existing ANSI X12-835 claim adjustment reason code 49, "These are non-covered services because this is a routine exam or screening procedure done in conjunction with a routine exam."

K. Ambulatory Surgical Center Facility Fee.--CPT code 45378, which is used to code a diagnostic colonoscopy, is on the list of procedures approved by Medicare for payment of an ambulatory surgical center (ASC) facility fee under §1833(I) of the Act. CPT code 45378 is currently assigned to ASC payment group 2. HCFA therefore added the new code G0105, colorectal cancer screening; colonoscopy on individual at high risk, to the ASC list effective for services furnished on or after January 1, 1998. HCFA believes that the facility services are the same whether the procedure is a screening or a diagnostic colonoscopy, and HCFA is, therefore, assigning code G0105 to payment group 2, which is the same payment rate assigned to CPT code 45378. If during the course of the screening colonoscopy performed at an ASC, 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 rather than code G0105.