
Medicare Hospital Manual

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

Transmittal 768

Date: FEBRUARY 5, 2001

REFER TO CHANGE REQUEST 1497

| <u>HEADER SECTION NUMBERS</u> | <u>PAGES TO INSERT</u> | <u>PAGES TO DELETE</u> |
|-------------------------------|-------------------------|-------------------------|
| 437.1 - 437.2 (Cont.) | 4-265 - 4-268.2 (6 pp.) | 4-265 - 4-268.2 (6 pp.) |

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

Section 437.1, Screening Pap Smears and Screening Pelvic Examinations, is being updated to reflect the Consolidated Appropriations Act of 2001, Public Law 106-554, which modifies current law to provide Medicare coverage for biennial screening Pap smears and pelvic exams.

This instruction also updates the applicable bill types and payment methods for these benefits.

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

437.1 Screening Pap Smears and Screening Pelvic Examinations.--

A. Screening Pap Smear.--Effective January 1, 1998, §4102 of the Balanced Budget Act (BBA) of 1997 (P.L. 105-33) amended §1861 (nn) of the Social Security Act (the Act) (42 USC 1395X(nn)) to include coverage every 3 years for a screening Pap smear or more frequent coverage for women (1) at high risk for cervical or vaginal cancer, or (2) of childbearing age who have had a Pap smear during any of the preceding 3 years indicating the presence of cervical or vaginal cancer or other abnormality. Effective July 1, 2001, the Consolidated Appropriations Act of 2001 (P.L. 106-554) modifies §1861(nn) to provide Medicare coverage for biennial screening Pap smears. Specifications for frequency limitations are defined below.

1. Coverage.--For claims with dates of service from January 1, 1998, through June 30, 2001, screening Pap smears are covered when ordered and collected by a doctor of medicine or osteopathy (as defined in §1861(r)(l) of the Act), or other authorized practitioner (e.g., a certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist, who is authorized under State law to perform the examination) under one of the following conditions:

o The beneficiary has not had a screening Pap smear test during the preceding 3 years (i.e., 35 months have passed following the month that the woman had the last covered Pap smear). (Use ICD-9-CM code V76.2, special screening for malignant neoplasm, cervix); or

o There is evidence (on the basis of her medical history or other findings) that she is of childbearing age and has had an examination that indicated the presence of cervical or vaginal cancer or other abnormalities during any of the preceding 3 years; or that she is at high risk of developing cervical or vaginal cancer (use ICD-9-CM code V15.89, other specified personal history presenting hazards to health). The high risk factors for cervical and vaginal cancer are:

Cervical Cancer High Risk Factors:

- Early onset of sexual activity (under 16 years of age);
- Multiple sexual partners (five or more in a lifetime);
- History of a sexually transmitted disease (including HIV infection); and
- Fewer than three negative Pap smears within the previous 7 years.

Vaginal Cancer High Risk Factors:

-- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

The term “woman of childbearing age” means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner, to be of childbearing age, based on her medical history or other findings. Payment is not made for a screening Pap smear for women at high risk or who qualify for coverage under the childbearing provision more frequently than once every 11 months after the month that the last screening Pap smear covered by Medicare was performed.

For claims with dates of service on or after July 1, 2001, when the beneficiary does not meet the criteria noted above for an annual screening Pap smear, pay for a screening Pap smear only after at least 23 months have passed following the month during which the beneficiary received her last covered screening Pap smear. All other coverage and payment requirements remain the same.

2. HCPCS Coding.--The following HCPCS codes are used for screening Pap smears:

o P3000--Screening papanicolaou smear, cervical or vaginal, up to three smears, by a technician under physician supervision.

- o G0123--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, evaluation by cytotechnologist under physician supervision.
- o G0143--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual evaluation and reevaluation by cytotechnologist under physician supervision.
- o G0144--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual evaluation and computer-assisted reevaluation by cytotechnologist under physician supervision.
- o G0145--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual evaluation and computer-assisted reevaluation using cell selection and review under physician supervision
- o G0147--Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision.
- o G0148--Screening cytopathology smears, cervical or vaginal, performed by automated system with manual reevaluation.

3. Payment.--Screening Pap smears are paid under the clinical diagnostic laboratory fee schedule with the exception of hospital-based RHCs/FQHCs which are paid as follows:

- o On an all inclusive rate for the professional component or;
- o Under the clinical diagnostic laboratory fee schedule for the technical component.

Deductible and coinsurance do not apply.

4. Billing Requirements.--The applicable bill types for screening Pap smears are 13X, 14X, and 85X. The applicable revenue code is 311.

Hospitals sometimes operate multi-purpose outpatient facilities based in the hospital, all or part of which may be certified by Medicare as an RHC/FQHC. These multi-purpose outpatient facilities bill for the professional component of the screening Pap smear under bill type 71X or 73X along with revenue code 52X and the technical component under bill type 13X, 14X, or 85X along with their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services) and revenue code 331 when billing their intermediary for this service.

B. Screening Pelvic Examinations.--Section 4102 of the BBA of 1997 (P.L. 105-33) amended §1861 (nn) of the Act (42 USC 1395X(nn)) to include coverage of a screening pelvic examination for all female beneficiaries, effective January 1, 1998. Effective July 1, 2001, the Consolidated Appropriations Act of 2001 (P.L. 106-554) modifies §1861(nn) to provide Medicare coverage for biennial screening pelvic examinations. Specifications for frequency limitations are defined below. A screening pelvic examination should include at least 7 of the following 11 elements:

- o Inspection and palpation of breasts for masses or lumps, tenderness, symmetry, or nipple discharge;
- o Digital rectal examination including sphincter tone, presence of hemorrhoids, and rectal masses;

Pelvic examination (with or without specimen collection for smears and culture) including:

- o External genitalia (for example, general appearance, hair distribution, or lesions);
 - o Urethral (for example, masses, tenderness, or scarring);
 - o Bladder (for example, fullness, masses, or tenderness);
 - o Vagina (for example, general appearance, estrogen effect, discharge, lesions, pelvic support, cystocele, or rectocele);
 - o Cervix (for example, general appearance, lesions or discharge);
 - o Uterus (for example, size, contour, position, mobility, tenderness, consistency, descent, or support);
 - o Adnexa/parametria (for example, masses, tenderness, organomegaly, or nodularity);
- and
- o Anus and perineum.

1. **Coverage.**--For claims with dates of service from January 1, 1998, through June 30, 2001, Medicare Part B pays for a screening pelvic examination if it is performed by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or by a certified nurse midwife (as defined in §1861 (gg) of the Act), or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861 (aa) of the Act) who is authorized under State law to perform the examination. This examination does not have to be ordered by a physician or other authorized practitioner.

Payment may be made for a screening pelvic examination performed on an asymptomatic woman only if the individual has not had a screening pelvic examination paid for by Medicare during the preceding 35 months following the month in which the last Medicare covered screening pelvic examination was performed. (Use ICD-9-CM code V76.2, special screening for malignant neoplasm, cervix, or code V76.49 for a patient who does not have a uterus or cervix.) Exceptions are as follows:

- o Payment may be made for a screening pelvic examination performed more frequently than once every 35 months if the test is performed by a physician or other practitioner and there is evidence that the woman is at high risk (on the basis of her medical history or other findings) of developing cervical cancer, or vaginal cancer. (Use ICD-9-CM code V15.89, other specified personal history presenting hazards to health.) The high risk factors for cervical and vaginal cancer are:

Cervical Cancer High Risk Factors:

- Early onset of sexual activity (under 16 years of age);
- Multiple sexual partners (five or more in a lifetime);
- History of a sexually transmitted disease (including HIV infection); and
- Fewer than three negative Pap smears within the previous 7 years.

Vaginal Cancer High Risk Factors:

-- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

o Payment may also be made for a screening pelvic examination performed more frequently than once every 36 months if the examination is performed by a physician or other practitioner, for a woman of childbearing age, who has had such an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term "women of childbearing age" means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner, to be of childbearing age, based on her medical history or other findings. Payment is not made for a screening pelvic examination for women at high risk or who qualify for coverage under the childbearing provision more frequently than once every 11 months after the month that the last screening pelvic examination covered by Medicare was performed.

o **For claims with dates of service on or after July 1, 2001**, if the beneficiary does not qualify for an annual screening pelvic exam as noted above, pay for the screening pelvic exam only after at least 23 months have passed following the month during which the beneficiary received her last covered screening pelvic exam. All other coverage and payment requirements remain the same.

2. HCPCS Coding--The following HCPCS code is used for screening pelvic examinations:

o G0101--Cervical or vaginal cancer screening pelvic and clinical breast examination.

3. Payment--**Screening pelvic examinations are paid under the outpatient prospective payment system (OPPS) with the exception of hospital-based RHCs/FQHCs which are paid as follows:**

- o **Payment is made on an all inclusive rate for the professional component or;**
- o **Under the OPPS for the technical component.**

The Part B deductible for screening pelvic examinations is waived effective January 1, 1998. Coinsurance applies.

4. Billing Requirements--The applicable bill types for screening pelvic examination (including breast examination) are **13X, 14X, and 85X. The applicable revenue code is 770.**

Hospitals sometimes operate multi-purpose outpatient facilities based in the hospital, all or part of which may be certified by Medicare as an RHC/FQHC. These multi-purpose outpatient facilities bill for the professional component of the screening pelvic examinations under bill type 71X or 73X along with revenue code 52X and the technical component under bill type 13X, 14X, or 85X along with the hospital outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services) and revenue code 770 when billing their intermediary for this service.

When a claim is received for a screening pelvic examination (including a clinical breast examination), performed on or after January 1, 1998, report special override Code 1 in field 65j "Special Action" of the CWF record to avoid application of the Part B deductible.

C. Screening Pap Smears and Screening Pelvic Examinations--

1. CWF Edits--CWF will edit for screening Pap smear and/or screening pelvic examination **performed more** frequently than allowed according to the presence of high risk factors.

2. Medicare Summary Notices (MSN) and Explanation of Your Medicare Benefits (EOMB) Messages.--If a screening Pap smear and/or screening pelvic examination is being denied because the procedure/examination is performed more frequently than allowed, use the following MSN or EOMB message:

“Medicare pays for screening Pap smear and/or screening pelvic examination only once every (2/3) years unless high risk factors are present.” (MSN Message 18-17, EOMB Message 18.26.)

3. Remittance Advice Notices.--If the screening Pap smear and/or screening pelvic examination is being denied because the procedure/examination is performed more frequently than allowed using existing American National Standard Institute (ANSI) X12-835 claim adjustment reason code 119, “Benefit maximum for this time period has been reached,” at the line level, along with line level remark code M83, “Service is not covered unless the beneficiary is classified as at high risk.”

437.2 Clinical Laboratory Improvement Amendments (CLIA).--CLIA of 1988 changes clinical laboratories' certification. Effective September 1, 1992, clinical laboratory services are paid only if the entity furnishing the services has been issued a CLIA number.

However, pay laboratories for a limited number of laboratory services if they have a CLIA certificate of waiver or certificate for physician-performed microscopy procedures. These laboratories are not subject to routine on-site surveys.

A. Verification Responsibilities.--You are responsible for verifying CLIA certification prior to ordering laboratory services under arrangements. The survey process validates that laboratory services are provided by approved laboratories.

B. CLIA Numbers.--Use the following CLIA positions:

- o Positions 1 and 2 of the CLIA number are the State code (based on the laboratory's physical location at time of registration);
- o Position 3 is an alpha letter "D"; and
- o Positions 4-10 are a unique number assigned by the CLIA billing system. (No other laboratory in the country has this number.)

C. Anatomical Pathology.--If you perform pathological services, bill them to your local carrier on a form HCFA-1500. Be sure to place your provider identification number (PIN) or the PIN of the hospital-based physician or group, depending upon the billing arrangements you have with the carrier, on each line item of the HCFA-1500.

D. Certificate for Physician-Performed Microscopy Procedures.--Effective January 19, 1993, a laboratory that holds a certificate for physician-performed microscopy procedures may perform only those tests specified as physician-performed microscopy procedures and waived tests, as described in 437.2 E., and no others. The following codes may be used:

| <u>HCPCS CODE</u> | <u>Test</u> |
|-------------------|--|
| Q0111 | Wet mounts, including preparations of vaginal, cervical or skin specimens; |
| Q0112 | All potassium hydroxide (KOH) preparations; |
| Q0113 | Pinworm examinations; |
| Q0114 | Fern test; |

Q0115 Post-coital direct, qualitative examinations of vaginal or cervical mucous; and

81015 Urine sediment examinations.

E. Certificate of Waiver.--Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver or certificate of registration to legally perform clinical laboratory testing anywhere in the United States.

Payment for covered laboratory services furnished on or after September 1, 1992, by laboratories that have a waiver is limited to the following eight procedures:

A grace period starting May 1, 1993, and ending on July 31, 1993, has been granted to allow providers time to adapt to the new coding system. Physicians, suppliers, and providers may submit claims for services furnished during this grace period with 1992 or 1993 lab codes.

Claims for services provided prior to the grace period (prior to May 1, 1993) must reflect 1992 codes, even if received after the end of the grace period (after July 1, 1993). Claims with dates of services prior to May 1, 1993, which reflect 1993 codes, are denied.

| <u>HCPCS Code</u> | <u>Test</u> |
|-------------------|--|
| <u>1992</u> | <u>1993</u> |
| Q0095 | 81025 Urine pregnancy test; visual color comparison tests; |
| Q0096 | 84830 Ovulation test; visual color comparison test for human luteinizing hormone; |
| Q0097 | 83026 Hemoglobin; by copper sulfate method, non-automated; |
| Q0098 | 82962 Glucose, blood; by glucose monitoring devices cleared by the FDA specifically for home use; |
| 82270 | 82270 Blood, occult; feces; |
| Q0100 | 81002 Urinalysis by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of constituents; non-automated, without microscopy; |
| Q0101 | 85013 Microhematocrit; spun; and |
| Q0102 | 85651 Sedimentation rate, erythrocyte; non-automated. |

Effective January 19, 1993, a ninth test was added to the waived test list:

Q0116 Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

F. Under Arrangements.--When you obtain laboratory tests for outpatients or nonpatients under arrangements with independent laboratories or other hospital laboratories, be sure that the laboratory performing the services has a CLIA number.

G. Certificate of Registration.--Initially, you are issued a CLIA number when you apply to the CLIA program.