Medicare
Intermediary Manual
Part 3 – Claims Process

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

Transmittal 1807 **Date: AUGUST 31, 2000**

CHANGE REQUEST 1254

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
3628.1 (Cont.) – 3628.2 (Cont.)	6-166.1 - 6-166.4 (4 pp.)	6-166.1 - 6-166.4 (4 pp.)

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

Section 3628.1, Screening Pap Smears and Screening Pelvic Examinations, is being updated to reflect the additional language to allow a screening pelvic examination for a woman who has had a hysterectomy with total removal of the cervix and to allow code V76.49 to be used for billing this type of screening.

The section is also being updated to reflect the allowance of a CORF to bill for screening pelvic examinations in accordance with PM-AB-00-39, dated May 2000.

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 previously published in the manual and is only being reprinted.

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. Deductible and coinsurance do not apply.

4. Billing Requirements.--The applicable bill types for screening Pap smears are 13X (hospital outpatient), 14X (hospital other, diagnostic clinical laboratory services to "nonpatients"), 23X (SNF outpatient), 24X (SNF other), or 71X (Rural Health Clinic). The applicable revenue code is 311.

B. Screening Pelvic Examinations.--Section 4102 of the BBA of 1997 (P.L. 105-33) amends §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. 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.--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 36 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.

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 on a reasonable cost basis. 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 (hospital outpatient, 14X (hospital other, diagnostic clinical laboratory services to "nonpatients"), 23X (SNF outpatient), 24X (SNF other), 71X (Rural Health Clinic), or 75X (CORF). The applicable revenue code is 770.

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 than once in 3 years and high risk factors are not present.

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 than once in 3 years and no high risk factors are present, use the following MSN or EOMB message:

"Medicare pays for screening Pap smear and/or screening pelvic examination only once every 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 than once in 3 years and no high risk factors are present, use 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."

3628.2 Clinical Laboratory Improvement Amendments (CLIA).--

A. Background.--CLIA of 1988 changes clinical laboratories' certification. Effective September 1, 1992, pay clinical laboratory services only if the entity furnishing laboratory services has been issued a CLIA number.

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

B. General.--For hospital, SNF, and hospice general inpatient care claims, providers are responsible for verifying CLIA certification prior to ordering laboratory services under arrangement. The survey process validates that laboratory services are provided by approved laboratories.

C. Other.--For HHA and renal dialysis facility claims, do not attempt to validate CLIA certification against payment. Freestanding HHAs and ESRD facilities cannot bill for laboratory tests. The survey process is used to validate that laboratory services in HHAs and ESRD facilities are being provided in accordance with the CLIA certificate. You do not need to take action.

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

o Positions 1 and 2 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 lab in the country will have this number.)

E. 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 §3628.2 subsection F, and no others. The following codes may be used:

HCPCS Code	Test
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.

F. 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.

A grace period starting May 1, 1993, and ending 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). Deny claims with dates of services prior to May 1, 1993, which reflect 1993 codes.

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

HCPCS Code		Test
1992	1993	
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;