

CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 48

Department of Health &
Human Services (DHHS)

Centers for Medicare &
Medicaid Services (CMS)

Date: MARCH 17, 2006

Change Request 4278

SUBJECT: Technical Corrections to the NCD Manual

I. SUMMARY OF CHANGES: We are making technical changes to correct for errors that occurred in converting the Coverage Issues Manual to the National Coverage Determination (NCD) Manual. We are also making changes to remove coding from the NCDs as the statute exempts coding from NCDs. Specifically, we are deleting the duplicative material in section 20.8.3, 150.4, 160.3, and 160.11. We have deleted the coding information from sections 40.2, 80.11, 140.1, 150.5, 210.1, 210.2, 260.1 and 300.1. We are removing utilization parameters that were not part of the CIM policy immediately prior to conversion to the NCD manual from section 20.29. We are removing a cross reference to a section deleted above from section 160.7.1. We are deleting inappropriate material from section 160.8. We are deleting duplicate information from section 190.2 and inserting a cross reference to the remaining location. We are restoring a portion of a sentence in limitation 7 in section 190.14 that was omitted in the manualization of the final rule announcing the policy that was developed under negotiated rulemaking. We are correcting typographical errors that occurred in the conversion of sections 230.8 and 230.19 from the CIM to the NCD Manual. We are deleting the material in section 270.1.1 that inadvertently was not removed when the updated policy on electrical stimulation for wound healing was promulgated in section 270.1.

NEW/REVISED MATERIAL

EFFECTIVE DATE: June 19, 2006

IMPLEMENTATION DATE: June 19, 2006

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. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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D	1/20.8.3/Anesthesia in Cardiac Pacemaker Monitors
R	1/20.29/Hyperbaric Oxygen Therapy
R	1/40.2/Home Glucose Monitors
R	1/80.11/Vitreectomy
R	1/140.1/Abortion
D	1/150.4/Neuromuscular Electrical Stimulator (NMES) in the Treatment of Disuse Atrophy
R	1/150.5/Diathermy Treatment
D	1/160.3/Assessing Patients Suitability for Electrical Nerve Stimulation
R	1/160.7.1/Assessing Patients Suitability for Electrical Nerve Stimulation Therapy
R	1/160.8/Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature
D	1/160.11/Osteogenic Stimulation
R	1/190.2/Diagnostic Pap Smears
R	1/190.14/Human Immunodeficiency Virus (HIV) Testing (Diagnosis)
R	1/Table of Contents
R	1/210.1/Prostate Cancer Screening Tests
R	1/210.2/Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer
R	1/230.8/Non-Implantable Pelvic Floor Electrical Stimulator
R	1/230.19/Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients
N	1/260.1/Adult Liver Transplantation
D	1/270.1.1/Electrostimulation in the Treatment of Wounds
R	1/300.1/Obsolete or Unreliable Diagnostic Tests

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03	Transmittal: 48	Date: March 17, 2006	Change Request 4278
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SUBJECT: Technical Corrections to the NCD Manual

I. GENERAL INFORMATION

A. Background: The CMS converted the Coverage Issues Manual (CIM) to the National Coverage Determinations (NCD) Manual in October 2003. The conversion was intended to occur without any changes to the language.

B. Policy: This manual transmittal corrects several errors that occurred in the conversion of the CIM to the NCD Manual. It also removes coding information from several sections in accordance with section 731 of the Medicare Modernization Act of 2003. This statutory provision excludes coding from NCDs. There are no system changes associated with this change request.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F	R	C	D	Shared System Maintainers				Other
						I	M	V	C	
		H	a	M	E	S	S	S	W	
		I	r	i	R	S	S	F	F	
4278.1	This CR correct typos and removes codes from the NCD Manual. There are no substantive changes associated with this CR and no system changes associated with this CR. Contractors should review any local publications to ensure they are consistent with national policy.	X	X	X	X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F	R	C	D	Shared System Maintainers				Other
						I	M	V	C	
		H	a	M	E	S	S	S	W	
		I	r	i	R	S	S	F	F	

20.29 – Hyperbaric Oxygen Therapy

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 35-10

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

A. Covered Conditions

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication,
2. Decompression illness,
3. Gas embolism,
4. Gas gangrene,
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis),
8. Acute peripheral arterial insufficiency,
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
11. Osteoradionecrosis as an adjunct to conventional treatment,
12. Soft tissue radionecrosis as an adjunct to conventional treatment,
13. Cyanide poisoning,
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
 - a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
 - b. Patient has a wound classified as Wagner grade III or higher; and
 - c. Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status,

optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B. Noncovered Conditions

All other indications not specified under §270.4(A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §270.4(A).

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers
2. Chronic peripheral vascular insufficiency
3. Anaerobic septicemia and infection other than clostridial
4. Skin burns (thermal).
5. Senility.
6. Myocardial infarction.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.
13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease)
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.
20. Multiple Sclerosis.
21. Arthritic Diseases.
22. Acute cerebral edema.

C. Topical Application of Oxygen

This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

Cross reference: §270.5 of this manual.

40.2 - Home Blood Glucose Monitors

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 60-11

There are several different types of blood glucose monitors that use reflectance meters to determine blood glucose levels. Medicare coverage of these devices varies, with respect to both the type of device and the medical condition of the patient for whom the device is prescribed.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use. However, some types of blood glucose monitors which use a reflectance meter specifically designed for home use by diabetic patients may be covered as durable medical equipment, subject to the conditions and limitations described below.

Blood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients for whom the device is indicated. Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels. Accordingly, coverage of home blood glucose monitors is limited to patients meeting the following conditions:

1. The patient has been diagnosed as having diabetes;
2. The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and
3. The device is designed for home rather than clinical use.

There is also a blood glucose monitoring system designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors described above. They differ by having such features as voice synthesizers, automatic timers, and specially

designed arrangements of supplies and materials to enable the visually impaired to use the equipment without assistance.

These special blood glucose monitoring systems are covered under Medicare if the following conditions are met:

- The patient and device meet the three conditions listed above for coverage of standard home blood glucose monitors; and
- The patient's physician certifies that he or she has a visual impairment severe enough to require use of this special monitoring system.

The additional features and equipment of these special systems justify a higher reimbursement amount than allowed for standard blood glucose monitors. Separately identify claims for such devices and establish a separate reimbursement amount for them.

80.11 - Vitrectomy

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM - 35-16

Vitrectomy may be considered reasonable and necessary for the following conditions: vitreous loss incident to cataract surgery, vitreous opacities due to vitreous hemorrhage or other causes, retinal detachments secondary to vitreous strands, proliferative retinopathy, and vitreous retraction. See chapter 23 of the Medicare Claims *Processing* Manual for how to determine payment for physician vitrectomy services and the Medicare Claims Processing Manual, Chapter 14, "Ambulatory Surgical Centers," §40, for how to determine payment for ASC facility vitrectomy services. Also, see the Medicare Claims Processing Manual, Chapter 23, "Fee Schedule Administration and Coding Requirements," §20.9, to identify when, for Medicare payment purposes, certain vitrectomy codes are included in other codes or when codes for other services include vitrectomy codes.

140.1 - Abortion

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 35-99

Abortions are not covered Medicare procedures except:

1. If the pregnancy is the result of an act of rape or incest; or
2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

150.5 - Diathermy Treatment

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 35-41

High energy pulsed wave diathermy machines have been found to produce some degree of therapeutic benefit for essentially the same conditions and to the same extent as standard diathermy. Accordingly, where the contractor's medical staff has determined that the pulsed wave diathermy apparatus used is one which is considered therapeutically effective, the treatments are considered a covered service, but only for those conditions for which standard diathermy is medically indicated and only when rendered by a physician or incident to a physician's professional services.

Cross-reference: [§240.3](#).

160.7.1 - Assessing Patients Suitability for Electrical Nerve Stimulation Therapy

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 35-46

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator.

Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. Transcutaneous Electrical Nerve Stimulation (TENS)

This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of one month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See [§160.13](#) for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain.

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

B. Percutaneous Electrical Nerve Stimulation (PENS)

This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by [§1862\(a\)\(1\)](#) of the Act. (See [§160.7](#) for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See [§280.13](#) for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

160.8 - Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 35-57

Electroencephalographic (EEG) monitoring is a safe and reliable technique for the assessment of gross cerebral blood flow during general anesthesia and is covered under Medicare. Very characteristic changes in the EEG occur when cerebral perfusion is inadequate for cerebral function. EEG monitoring as an indirect measure of cerebral perfusion requires the expertise of an electroencephalographer, a neurologist trained in EEG, or an advanced EEG technician for its proper interpretation.

The EEG monitoring may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted.

190.2 - Diagnostic Pap Smears

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 50-20, CIM 50-20.1

A diagnostic pap smear and related medically necessary services are covered under Medicare Part B when ordered by a physician under one of the following conditions:

- Previous cancer of the cervix, uterus, or vagina that has been or is presently being treated;
- Previous abnormal pap smear;
- Any abnormal findings of the vagina, cervix, uterus, ovaries, or adnexa;
- Any significant complaint by the patient referable to the female reproductive system; or
- Any signs or symptoms that might in the physician's judgment reasonably be related to a gynecologic disorder.

Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer. *(See section 210.2.)*

190.14 - Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

PM AB-02-100

Diagnosis of HIV infection is primarily made through the use of serologic assays. These assays take one of two forms: antibody detection assays and specific HIV antigen (p24) procedures. The antibody assays are usually enzyme immunoassays (EIA), which are used to confirm exposure of an individual's immune system to specific viral antigens. These assays may be formatted to detect HIV-1, HIV-2, or HIV-1 and 2 simultaneously and to detect both IgM and IgG. When the initial EIA test is repeatedly positive or indeterminate, an alternative test is used to confirm the specificity of the antibodies to individual viral components. The most commonly used method is the Western Blot.

The HIV-1 core antigen (p24) test detects circulating viral antigen which may be found prior to the development of antibodies and may also be present in later stages of illness in the form of recurrent or persistent antigenemia. Its prognostic utility in HIV infection has been diminished as a result of development of sensitive viral RNA assays, and its primary use today is as a routine screening tool in potential blood donors.

In several unique situations, serologic testing alone may not reliably establish an HIV infection. This may occur because the antibody response (particularly the IgG response detected by Western Blot) has not yet developed (that is, acute retroviral syndrome) or is persistently equivocal because of inherent viral antigen variability. It is also an issue in perinatal HIV infection due to transplacental passage of maternal HIV antibody. In these situations, laboratory evidence of HIV in blood by culture, antigen assays, or proviral DNA or viral RNA assays, is required to establish a definitive determination of HIV infection.

Indications

Diagnostic testing to establish HIV infection may be indicated when there is a strong clinical suspicion supported by one or more of the following clinical findings:

1. The patient has a documented, otherwise unexplained, AIDS-defining or AIDS-associated opportunistic infection.
2. The patient has another documented sexually transmitted disease, which identifies significant risk of exposure to HIV and the potential for an early or subclinical infection.
3. The patient has documented acute or chronic hepatitis B or C infection that identifies a significant risk of exposure to HIV and the potential for an early or subclinical infection.
4. The patient has a documented AIDS-defining or AIDS-associated neoplasm.
5. The patient has a documented AIDS-associated neurologic disorder or otherwise unexplained dementia.
6. The patient has another documented AIDS-defining clinical condition, or a history of other severe, recurrent, or persistent conditions which suggest an underlying immune deficiency (for example, cutaneous or mucosal disorders).
7. The patient has otherwise unexplained generalized signs and symptoms suggestive of a chronic process with an underlying immune deficiency (for example, fever, weight loss, malaise, fatigue, chronic diarrhea, failure to thrive, chronic cough, hemoptysis, shortness of breath, or lymphadenopathy).

8. The patient has otherwise unexplained laboratory evidence of a chronic disease process with an underlying immune deficiency (for example, anemia, leukopenia, pancytopenia, lymphopenia, or low CD4+ lymphocyte count).

9. The patient has signs and symptoms of acute retroviral syndrome with fever, malaise, lymphadenopathy, and skin rash,

10. The patient has documented exposure to blood or body fluids known to be capable of transmitting HIV (for example, needlesticks and other significant blood exposures) and antiviral therapy is initiated or anticipated to be initiated.

11. The patient is undergoing treatment for rape. (HIV testing is part of the rape treatment protocol.)

Limitations

1. HIV antibody testing in the United States is usually performed using HIV-1 or HIV-1/2 combination tests. HIV-2 testing is indicated if clinical circumstances suggest HIV-2 is likely (that is, compatible clinical finding and HIV-1 test negative). HIV-2 testing may also be indicated in areas of the country where there is greater prevalence of HIV-2 infections.

2. The Western Blot test should be performed only after documentation that the initial EIA tests are repeatedly positive or equivocal on a single sample.

3. The HIV antigen tests currently have no defined diagnostic usage.

4. Direct viral RNA detection may be performed in those situations where serologic testing does not establish a diagnosis but strong clinical suspicion persists (for example, acute retroviral syndrome, nonspecific serologic evidence of HIV, or perinatal HIV infection).

5. If initial serologic tests confirm an HIV infection, repeat testing is not indicated.

6. If initial serologic tests are HIV EIA negative and there is no indication for confirmation of infection by viral RNA detection, the interval prior to retesting is 3-6 months.

7. Testing for evidence of HIV infection using serologic methods may be medically appropriate in situations where there is a risk of exposure to HIV. *However, in the absence of a documented AIDS defining or HIV-associated disease, an HIV-associated sign or symptom, or documented exposure to a known HIV-infected source, the testing is considered by Medicare to be screening and thus is not covered by Medicare (for example, history of multiple blood component transfusions, exposure to blood or body fluids not resulting in consideration of therapy, history of transplant, history of illicit drug*

use, multiple sexual partners, same-sex encounters, prostitution, or contact with prostitutes).

8. The CPT Editorial Panel has issued a number of codes for infectious agent detection by direct antigen or nucleic acid probe techniques that have not yet been developed or are only being used on an investigational basis. Laboratory providers are advised to remain current on FDA-approved status for these tests.

**Medicare National Coverage
Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations**

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(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

230.8 - Non-Implantable Pelvic *Floor* Electrical Stimulator

210.1 - Prostate Cancer Screening Tests

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 50-55

Covered

A. General

Section 4103 of the Balanced Budget Act of 1997 provides for coverage of certain prostate cancer screening tests subject to certain coverage, frequency, and payment limitations. Medicare will cover prostate cancer screening tests/procedures for the early detection of prostate cancer. Coverage of prostate cancer screening tests includes the following procedures furnished to an individual for the early detection of prostate cancer:

- Screening digital rectal examination; and
- Screening prostate specific antigen blood test.

B. Screening Digital Rectal Examinations

Screening digital rectal examinations are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening digital rectal examination was performed). Screening digital rectal examination means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate. This screening must be performed by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or by a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in §1861(aa) and §1861(gg) of the Act) who is authorized under State law to perform the examination, fully knowledgeable about the beneficiary's medical condition, and would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.

C. Screening Prostate Specific Antigen Tests

Screening prostate specific antigen tests are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening prostate specific antigen test was performed). Screening prostate specific antigen tests (PSA) means a test to detect the marker for adenocarcinoma of prostate. PSA is a reliable immunocytochemical marker for primary and metastatic adenocarcinoma of prostate. This screening must be ordered by the beneficiary's physician or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (the term "attending physician" is defined in §1861(r)(1) of the Act to mean a doctor of medicine or osteopathy and the terms "physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife" are defined in §1861(aa) and §1861(gg) 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 (test) performed in the overall management of the beneficiary's specific medical problem.

210.2 - Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 50-20.1

Screening Pap Smear

A screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and pelvic examination (including clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- She has not had such a test during the preceding *two* years or is a woman of childbearing age (§1861(nn) of the Act).
- There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every *two* years.

High risk factors for cervical and vaginal cancer are:

- Early onset of sexual activity (under 16 years of age)
- Multiple sexual partners (five or more in a lifetime)
- History of sexually transmitted disease (including HIV infection)
- Fewer than three negative or any pap smears within the previous seven years; and
- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

NOTE: Claims for pap smears must indicate the beneficiary's low or high risk status by including the appropriate ICD-9-CM on the line item (Item 24E of the Form CMS-1500).

Definitions

- A woman as described in §1861(nn) of the Act is a woman who is of childbearing age and has had a pap smear test during any of the preceding three years that indicated the presence of cervical or vaginal cancer or other abnormality, or is at high risk of developing cervical or vaginal cancer.
- A woman of childbearing age is one who is premenopausal and has been determined by a physician or other qualified practitioner to be of childbearing age, based upon the medical history or other findings.

- Other qualified practitioner, as defined in 42 CFR 410.56(a) includes 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.

Screening Pelvic Examination

Section 4102 of the Balanced Budget Act of 1997 provides for coverage of screening pelvic examinations (including a clinical breast examination) for all female beneficiaries, subject to certain frequency and other limitations. A screening pelvic examination (including a clinical breast examination) should include at least seven of the following eleven elements:

- Inspection and palpation of breasts for masses or lumps, tenderness, symmetry, or nipple discharge.

- Digital rectal examination including sphincter tone, presence of hemorrhoids, and rectal masses. Pelvic examination (with or without specimen collection for smears and cultures) including:

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

This description is from Documentation Guidelines for Evaluation and Management Services, published in May 1997 and was developed by the Centers for Medicare & Medicaid Services and the American Medical Association.

230.8 - Non-Implantable Pelvic *Floor* Electrical Stimulator

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 60-24

Non-implantable pelvic floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator.

The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient's clinical diagnosis.

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

230.19 - Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 45-32

Carnitine is a naturally occurring substance that functions in the transport of the long-chain fatty acids for energy production by the body. Deficiency can occur due to a congenital defect in synthesis or utilization, or from dialysis. The causes of carnitine deficiency in hemodialysis patients include dialytic loss, reduced renal synthesis and reduced dietary intake.

Intravenous levocarnitine, for one of the following indications, will only be covered for those ESRD patients who have been on dialysis for a minimum of three months. Patients must have documented carnitine deficiency, defined as a plasma free carnitine level < 40 micromol/L (determined by a professionally accepted method as recognized in current literature), along with signs and symptoms of:

- *Erythropoietin*-resistant anemia (persistent *hematocrit* < 30 percent with treatment) that has not responded to standard erthropoietin dosage (that which is

considered clinically appropriate to treat the particular patient) with iron replacement, and for which other causes have been investigated and adequately treated, or

- *Hypotension* on hemodialysis that interferes with delivery of the intended dialysis despite application of usual measures deemed appropriate (e.g., fluid management). Such episodes of hypotension must have occurred during at least 2 dialysis treatments in a 30-day period.

Continued use of levocarnitine will not be covered if improvement has not been demonstrated within 6 months of initiation of treatment. All other indications for levocarnitine are noncovered in the ESRD population.

For a patient currently receiving intravenous levocarnitine, Medicare will cover continued treatment if:

- Levocarnitine has been administered to treat erythropoietin-resistant anemia (persistent hematocrit < 30 percent with treatment) that has not responded to standard erythropoietin dosage (that which is considered clinically appropriate to treat the particular patient) with iron replacement, and for which other causes have been investigated and adequately treated, or hypotension on hemodialysis that interferes with delivery of the intended dialysis despite application of usual measures deemed appropriate (e.g., fluid management) and such episodes of hypotension occur during at least 2 dialysis treatments in a 30-day period; and

- The patient's medical record documents a pre-dialysis plasma free carnitine level < 40 micromol/L prior to the initiation of treatment; or

- The treating physician certifies (documents in the medical record) that in his/her judgment, if treatment with the levocarnitine is discontinued, the patient's pre-dialysis carnitine level would fall below 40 micromol/L and the patient would have recurrent erythropoietin-resistant-anemia or intradialytic hypotension.

260.1 - Adult Liver Transplantation

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 35-53

A. General

Effective July 15, 1996, adult liver transplantation when performed on beneficiaries with end stage liver disease other than hepatitis B or malignancies is covered under Medicare when performed in a facility which is approved by CMS as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation when performed on beneficiaries with end stage liver disease other than malignancies is covered under Medicare when

performed in a facility which is approved by CMS as meeting institutional coverage criteria.

Effective September 1, 2001, Medicare covers adult liver transplantation for hepatocellular carcinoma when the following conditions are met:

- The patient is not a candidate for subtotal liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement;
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and
- The transplant is furnished in a facility that is approved by CMS as meeting institutional coverage criteria for liver transplants (see 65 FR 15006).

Adult liver transplantation for other malignancies remains excluded from coverage. Coverage of adult liver transplantation is effective as of the date of the facility's approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See "Federal Register" 56 FR 15006 dated April 12, 1991.)

B. Follow-Up Care

Follow-up care or retransplantation required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving noncovered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines.

C. Immunosuppressive Drugs

See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.5.1 and the Medicare Claims Processing Manual, Chapter 17, "Drugs and Biologicals," §80.3.

300.1 - Obsolete or Unreliable Diagnostic Tests

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)

CIM 50-34

A. Diagnostic Tests

Do not routinely pay for the following diagnostic tests because they are obsolete and have been replaced by more advanced procedures. The listed tests may be paid for only if the medical need for the procedure is satisfactorily justified by the physician who performs it. When the services are subject to the Quality Improvement Organization (QIO) Review, the QIO is responsible for determining that satisfactory medical justification exists.

When the services are not subject to QIO Review, the intermediary or carrier is responsible for determining that satisfactory medical justification exists. This includes:

- Amylase, blood isoenzymes, electrophoretic,
- Chromium, blood,
- Guanase, blood,
- Zinc sulphate turbidity, blood,
- Skin test, cat scratch fever,
- Skin test, lymphopathia venereum,
- Circulation time, one test,
- Cephalin flocculation,
- Congo red, blood,
- Hormones, adrenocorticotropin quantitative animal tests,
- Hormones, adrenocorticotropin quantitative bioassay,
- Thymol turbidity, blood,
- Skin test, actinomycosis,
- Skin test, brucellosis,
- Skin test, psittacosis,
- Skin test, trichinosis,
- Calcium, feces, 24-hour quantitative,
- Starch, feces, screening,
- Chymotrypsin, duodenal contents,
- Gastric analysis, pepsin,
- Gastric analysis, tubeless,
- Calcium saturation clotting time,
- Capillary fragility test (Rumpel-Leede),
- Colloidal gold,
- Bendien's test for cancer and tuberculosis,
- Bolen's test for cancer,
- Rehfuss test for gastric acidity, and
- Serum seromuroid assay for cancer and other diseases.

B. Cardiovascular Tests

Do not pay for the following phonocardiography and vectorcardiography diagnostic tests because they have been determined to be outmoded and of little clinical value. They include:

- Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician),
- Phonocardiogram; tracing only, without interpretation and report (e.g., when equipment is supplied by the hospital, clinic),
- Phonocardiogram; interpretation and report,

- Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report,
- Phonocardiogram; without interpretation and report,
- Phonocardiogram; interpretation and report only,
- Intracardiac,
- Vectorcardiogram (VCG), with or without ECG; with interpretation and report,
- Vectorcardiogram; tracing only, without interpretation and report, and
- Vectorcardiogram; interpretation and report only.