Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

Table of Contents

(Rev.18, 07-30-04)
(Rev. 24, 10-01-04)

230.11 - Diagnostic Pap Smears
230.12 - Dimethyl Sulfoxide (DMSO)
230.13 - Peridex CAPD Filter Set
230.14 - Ultrafiltration Monitor
230.15 - Electrical Continence Aid
230.16 - Bladder Stimulators (Pacemakers)
230.17 - Urinary Drainage Bags
230.18 - Sacral Nerve Stimulation for Urinary Incontinence
230.19 - Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients
240 - Respiratory System
240.1 - Lung Volume Reduction Surgery (Reduction Pneumoplasty)
240.2 - Home Use of Oxygen
240.3 - Heat Treatment, Including the Use of Diathermy and Ultra-Sound for Pulmonary Conditions
240.4 - Continuous Positive Airway Pressure (CPAP)
240.5 - Intrapulmonary Percussive Ventilator (IPV)
240.6 - Transvenous (Catheter) Pulmonary Embolectomy
240.7 - Postural Drainage Procedures and Pulmonary Exercises
250 - Skin
    250.1 - Treatment of Psoriasis
250.2 - Hemorheograph
250.3 - Intravenous Immune Globulin for the Treatment of Autoimmune Mucutaneous Blistering Diseases
250.4 - Treatment of Actinic Keratosis
260 - Transplantation - Solid Organ Transplants
260.1 - Adult Liver Transplantation
260.2 - Pediatric Liver Transplantation
260.3 - Pancreas Transplants
    260.3.1 – Islet Cell Transplantation in the Context of a Clinical Trial
260.4 - Reserved
260.5 - Intestinal and Multi-Visceral Transplantation
260.6 - Dental Examination Prior to Kidney Transplantation
260. 7 - Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine)
260.8 - Reserved
260.9 - Heart Transplants
270 - Wound Treatment
270.1 - Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds – (Effective July 1, 2004)
        270.1.1 - Electrical Stimulation for the Treatment of Wounds
270.2 - Noncontact Normothermic Wound Therapy (NNWT)
270.3 - Blood-Derived Products for Chronic Non-Healing Wounds – (Effective 07-23-04)
270.4 - Treatment of Decubitus Ulcers
270.5 - Porcine Skin and Gradient Pressure Dressings
280 - Medical and Surgical Supplies

280.1 - Durable Medical Equipment Reference List
280.2 - White Cane for Use by a Blind Person
280.3 - Specially Sized Wheelchairs
280.4 - Seat Lift
280.5 - Safety Roller
280.6 - Pneumatic Compression Devices
280.7 - Hospital Beds
280.8 - Air-Fluidized Bed
280.9 - Power Operated Vehicles That May Be Used as Wheelchairs
280.10 - Prosthetic Shoe
280.11 - Corset Used as Hernia Support
280.12 - Sykes Hernia Control
280.13 - Transcutaneous Electrical Nerve Stimulators (TENS)
280.14 – Infusion Pumps
290 - Nursing Services
290.1 - Home Health Visits to a Blind Diabetic
290.2 - Home Health Nurses' Visits to Patients Requiring Heparin Injections
300 - Diagnostic Tests Not Otherwise Classified
    300.1 - Obsolete or Unreliable Diagnostic Tests
310 - Clinical Trials
    310.1 - Routine Costs in Clinical Trails

200 - Pharmacology
(Rev. 1, 10-03-03)

No coverage determinations

210 - Prevention
(Rev. 1, 10-03-03)

210.1 - Prostate Cancer Screening Tests
(Rev. 1, 10-03-03)
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 (HCPCS code G0102) 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 (code G0103) 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. 1, 10-03-03)
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 three 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 three 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).

V76.2, special screening for malignant neoplasms of the cervix, indicates low risk; and

V15.89, other specified personal history presenting hazards to health, indicates high risk.

If pap smear or pelvic exam claims do not point to one of these diagnosis codes, the claim will reject in the Common Working File. Claims can contain up to four diagnosis codes, but the one pointed to on the line item must be either V76.2 or V15.89.

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.

210.3 – Colorectal Cancer Screening Tests
(Rev. 5, 12-19-03)

Section 4104 of the Balanced Budget Act of 1997 provides for coverage of screening colorectal cancer procedures under Medicare Part B. Medicare currently covers:

(1) annual fecal occult blood tests (FOBTs); (2) flexible sigmoidoscopy over 4 years; (3) screening colonoscopy for persons at average risk for colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years; (4) barium enema every 4 years as an alternative to flexible sigmoidoscopy, or every 2 years as an alternative to colonoscopy for persons at high risk for colorectal cancer; and, (5) other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.

Coverage of the above screening examinations was implemented in regulations through a final rule that was published on October 31, 1997 (62 FR 59079), and was effective January 1, 1998. At that time, based on consultation with appropriate experts and organizations, the definition of the term "FOBT" was defined in 42 CFR §410.37(a)(2) of the regulation to mean a "guaiac-based test for peroxidase activity, testing two samples from each of three consecutive stools."

In the 2003 Physician Fee Schedule Final Rule (67 FR 79966) effective March 1, 2003, CMS amended the FOBT screening test regulation definition at 42 CFR §410.37(a)(2) to provide that it could include either: (1) a guaiac-based FOBT, or, (2) other tests determined by the Secretary through a national coverage determination.

Covered Indications

Fecal Occult Blood Tests (FOBT) (effective for services performed on or after January 1, 2004)

1. History

FOBTs are generally divided into two types: immunoassay and guaiac types. Immunoassay (or immunochemical) fecal occult blood tests (iFOBT) use "antibodies directed against human globin epitopes. While most iFOBTs use spatulas to collect stool samples, some use a brush to collect toilet water surrounding the stool. Most iFOBTs require laboratory processing.

Guaiac fecal occult blood tests (gFOBT) use a peroxidase reaction to indicate presence of the heme portion of hemoglobin. "Guaiac turns blue after oxidation by oxidants or peroxidases in the presence of an oxygen donor such as hydrogen peroxide. Most FOBTs use sticks to collect stool samples and may be developed in a physician's office or a laboratory. In 1998, Medicare began reimbursement for guaiac FOBTs, but not immunoassay type tests for colorectal cancer screening. Since the fundamental process is similar for other iFOBTs, CMS evaluated colorectal cancer screening using immunoassay FOBTs in general.

2. Expanded Coverage

Medicare covers one screening FOBT per annum for the early detection of colorectal cancer. This means that Medicare will cover one guaiac-based (gFOBT) or one immunoassay-based (iFOBT) at a frequency of every 12 months; i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed, for beneficiaries aged 50 years and older. The beneficiary completes the existing gFOBT by taking samples from two different sites of three consecutive stools; the beneficiary completes the iFOBT by taking the appropriate number of stool samples according to the specific manufacturer's instructions. This screening requires a written order from the beneficiary's attending physician. ("Attending physician means a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Social Security 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.)

Noncovered Indications

All other indications for colorectal cancer screening not otherwise specified above remain noncovered.

210.4 – Cardoiovascular Screening Blood Tests

220 - Radiology

220.1 - Computerized Tomography

(Rev. 1, 10-03-03)
CIM 50-12

A - General

Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient; and (2) performed on a model of CT equipment that meets the criteria in C below.

CT scans have become the primary diagnostic tool for many conditions and symptoms. CT scanning used as the primary diagnostic tool can be cost effective because it can eliminate the need for a series of other tests, is noninvasive and thus virtually eliminates complications, and does not require hospitalization.

B - Determining Whether a CT Scan Is Reasonable and Necessary

Sufficient information must be provided with claims to differentiate CT scans from other radiology services and to make coverage determinations. Carefully review claims to insure that a scan is reasonable and necessary for the individual patient; i.e., the use must be found to be medically appropriate considering the patient's symptoms and preliminary diagnosis.

There is no general rule that requires other diagnostic tests to be tried before CT scanning is used. However, in an individual case the contractor's medical staff may determine that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient's symptoms or complaints stated on the claim form; e.g., "periodic headaches."

Claims for CT scans are reviewed for evidence of abuse which might include the absence of reasonable indications for the scans, an excessive number of scans or unnecessarily expensive types of scans considering the facts in the particular cases.

C - Approved Models of CT Equipment-

1 - Criteria for Approval

In the absence of evidence to the contrary, the contractor may assume that a CT scan for which payment is requested has been performed on equipment that meets the following criteria:

a - The model must be known to the Food and Drug Administration, and

b - Must be in the full market release phase of development.

Should it be necessary to confirm that those criteria are met, ask the manufacturer to submit the information in C.2. If manufacturers inquire about obtaining Medicare approval for their equipment, inform them of the foregoing criteria.

2 - Evidence of Approval

a - The letter sent by the Bureau of Radiological Health, Food and Drug Administration (FDA), to the manufacturer acknowledging the FDA's receipt of information on the specific CT scanner system model submitted as required under Public Law 90-602, "The Radiation Control for Health and Safety Act of 1968."

b - A letter signed by the chief executive officer or other officer acting in a similar capacity for the manufacturer which:

1 - Furnishes the CT scanner system model number, all names that hospitals and physicians' offices may use to refer to the CT scanner system on claims, and the accession number assigned by FDA to the specific model;

2 - Specifies whether the scanner performs head scans only, body scans only (i.e., scans of parts of the body other than the head), or head and body scans;

3 - States that the company or corporation is satisfied with the results of the developmental stages that preceded the full market release phase of the equipment, that the equipment is in the full market release phase, and the date on which it was decided to put the product into the full market release phase.

D - Mobile CT Equipment

CT scans performed on mobile units are subject to the same Medicare coverage requirements applicable to scans performed on stationary units, as well as certain health and safety requirements recommended by Health Resources and Services Administration (HRSA). As with scans performed on stationary units, the scans must be determined medically necessary for the individual patient. The scans must be performed on types of CT scanning equipment that have been approved for use as stationary units (see C above), and must be in compliance with applicable State laws and regulations for control of radiation.

1 - Hospital Setting

The hospital must assume responsibility for the quality of the scan furnished to inpatients and outpatients and must assure that a radiologist or other qualified physician is in charge of the procedure. The radiologist or other physician (i.e., one who is with the mobile unit) who is responsible for the procedure must be approved by the hospital for similar privileges.

2 - Ambulatory Setting

If mobile CT scan services are furnished at an ambulatory health care facility other than a hospital-based facility, e.g., a freestanding physician-directed clinic, the diagnostic procedure must be performed by or under the direct personal supervision of a radiologist or other qualified physician. In addition, the facility must maintain a record of the attending physician's order for a scan performed on a mobile unit.

3 - Billing for Mobile CT Scans

Hospitals, hospital-associated radiologists, ambulatory health care facilities, and physician owner/operators of mobile units may bill for mobile scans as they would for scans performed on stationary equipment.

4 - Claims Review

Evidence of compliance with applicable State laws and regulations for control of radiation should be requested from owners of mobile CT scan units upon receipt of the first claims. All mobile scan claims should be reviewed very carefully in accordance with instructions applicable to scans performed on fixed units, with particular emphasis on the medical necessity for scans performed in an ambulatory setting.

E - Multi-Planar Diagnostic Imaging (MPDI)

In usual computerized tomography (CT) scanning procedures, a series of transverse or axial images are reproduced. These transverse images are routinely translated into coronal and/or sagittal views. Multi-planar diagnostic imaging (MPDI) is a process which further translates the data produced by CT scanning by providing reconstructed oblique images which can contribute to diagnostic information. MPDI, also known as planar image reconstruction or reformatted imaging, is covered under Medicare when provided as a service to an entity performing a covered CT scan.

220.2 - Magnetic Resonance Imaging

(Rev.21, Issued: 09-10-04, Effective: As Noted, Implementation: 09-10-04)

A. General

1. Method of Operation

Magnetic resonance imaging *(MRI), formerly called nuclear magnetic resonance (NMR),* is a noninvasive method of graphically representing the distribution of water and other hydrogen-rich molecules in the human body. In contrast to conventional radiographs or *computed tomography (*CT) scans, in which the image is produced by x-ray beam attenuation by an object, MRI is capable of producing images by several techniques. In fact, various combinations of MR*I* production methods may be employed to emphasize particular characteristics of the tissue or body part being examined. The basic elements by which MRI produces an image are the density of hydrogen nuclei in the object being examined, their motion, the relaxation times, *and* the period of time required for the nuclei to return to their original states in the main, static magnetic field after being subjected to a brief additional magnetic field. These relaxation times reflect the physical-chemical properties of tissue and the molecular environment of its hydrogen nuclei. Only hydrogen atoms are present in human tissues in sufficient concentration for current use in clinical MRI.

2. General Clinical Utility

Overall, MRI is a useful diagnostic imaging modality that is capable of demonstrating a wide variety of soft-tissue lesions with contrast resolution equal or superior to CT scanning in various parts of the body.

Among the advantages of MRI are the absence of ionizing radiation and the ability to achieve high levels of tissue contrast resolution without injected iodinated radiological contrast agents. Recent advances in technology have resulted in development and *Food and Drug Administration (*FDA) approval of new paramagnetic contrast agents for MRI *that* allow even better visualization in some instances. Multi-slice imaging and the ability to image in multiple planes, especially sagittal and coronal, have provided flexibility not easily available with other modalities. Because cortical (outer layer) bone and metallic prostheses do not cause distortion of MRI, it has been possible to visualize certain lesions and body regions with greater certainty than has been possible with CT. The use of MRI on certain soft tissue structures for the purpose of detecting disruptive, neoplastic, degenerative, or inflammatory lesions has now become established in medical practice.

B. Nationally Covered Indications (Effective November 22, 1985)

Although several uses of MRI are still considered investigational and some uses are clearly contraindicated, MRI is considered medically efficacious for a number of uses. Use the following descriptions as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific cover*ed indications.* **Coverage is limited to MRI units** *that* **have FDA premarket approval, and such units must be operated within the parameters specified by the approval.** *In addition,* the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

The MRI is useful in examining the head, central nervous system, and spine. Multiple sclerosis can be diagnosed with MRI and the contents of the posterior fossa are visible. The inherent tissue contrast resolution of MRI makes it an appropriate standard diagnostic modality for general neuroradiology.

The MRI can assist in the differential diagnosis of mediastinal and retroperitoneal masses, including abnormalities of the large vessels such as aneurysms and dissection. When a clinical need exists to visualize the parenchyma of solid organs to detect anatomic disruption or neoplasia, this can be accomplished in the liver, urogenital system, adrenals, and pelvic organs without the use of radiological contrast materials. When MRI is considered reasonable and necessary, the use of paramagnetic contrast materials may be covered as part of the study. MRI may also be used to detect and stage pelvic and retroperitoneal neoplasms and to evaluate disorders of cancellous bone and soft tissues. It may also be used in the detection of pericardial thickening. Primary and secondary bone neoplasm and aseptic necrosis can be detected at an early stage and monitored with MRI. Patients with metallic prostheses, especially of the hip, can be imaged in order to detect the early stages of infection of the bone to which the prosthesis is attached.

Disc Disease Diagnosis (Effective March 22, 1994)

The MRI may also be covered to diagnose disc disease without regard to whether radiological imaging has been tried first to diagnose the problem.

Gating Devices and Surface Coils *(Effective March 4,1991)*

Gating devices *that* eliminate distorted images caused by cardiac and respiratory movement cycles are now considered state-of-the-art techniques and may be covered. Surface and other specialty coils may also be covered, as they are used routinely for high resolution imaging where small limited regions of the body are studied. They produce high signal-to-noise ratios resulting in images of enhanced anatomic detail.

C. Contraindications and Nationally Noncovered Indications

1. Contraindications

The MRI is not covered when the following patient-specific contraindications are present. It is not covered for patients with cardiac pacemakers or with metallic clips on vascular aneurysms. MRI during a viable pregnancy is also contraindicated at this time. The danger inherent in bringing ferromagnetic materials within range of MRI units generally constrains the use of MRI on acutely ill patients requiring life support systems and monitoring devices *that* employ ferromagnetic materials. In addition, the long imaging time and the enclosed position of the patient may result in claustrophobia, making patients who have a history of claustrophobia unsuitable candidates for MRI procedures.

2. *Nationally Noncovered Indications*

The CMS has determined that blood flow measurement, imaging of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Social Security Act, and are therefore noncovered.

D. Other

All other uses of MRI for which CMS has not specifically indicated coverage or noncoverage continue to be eligible for coverage through individual local contractor discretion.

(This NCD last reviewed September 2004.)

220.2.1 - Magnetic Resonance Spectroscopy

(Rev.21, Issued: 09-10-04, Effective: 09-10-04, Implementation: 09-10-04)

A. General

Magnetic Resonance Spectroscopy (MRS) is an application of magnetic resonance imaging (MRI). It is a non-invasive diagnostic test that uses strong magnetic fields to measure and analyze the chemical composition of human tissues. On March 22, 1994, CMS considered MRS an investigational procedure and issued a national noncoverage determination for all indications of MRS.

B. Nationally Covered Indications

Not applicable.

C. Nationally Noncovered Indications

After thorough review and reconsideration of the existing national noncoverage determination for MRS, as well as the available evidence for the use of MRS as a diagnostic tool for distinguishing indeterminate brain lesions, and/or as an aid in conducting brain biopsies, CMS has determined that the evidence is not adequate to conclude that MRS is reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act, for use in the diagnosis of brain tumors. Therefore, CMS reaffirms its current national noncoverage determination for all indications of MRS.

D. Other

Not applicable.

(This NCD last reviewed September 2004.)

220.3 - Magnetic Resonance Angiography

(Rev.21, Issued: 09-10-04, Effective: As Noted, Implementation: 09-10-04)

A. General

Magnetic resonance angiography (MRA) is a non-invasive diagnostic test that is an application of magnetic resonance imaging (MRI). By analyzing the amount of energy released from tissues exposed to a strong magnetic field, MRA provides images of normal and diseased blood vessels as well as visualization and quantification of blood flow through these vessels.

Phase contrast (PC) and time-of-flight (TOF) are the available MRA techniques at the time these instructions are being issued. PC measures the difference between the phases of proton spins in tissue and blood and measures both the venous and arterial blood flow at any point in the cardiac cycle. TOF measures the difference between the amount of magnetization of tissue and blood and provides information on the structure of blood vessels, thus indirectly indicating blood flow. Two-dimensional (2D) and three-dimensional (3D) images can be obtained using each method.

Contrast-enhanced MRA (CE-MRA) involves blood flow imaging after the patient receives an intravenous injection of a contrast agent. Gadolinium, a non-ionic element, is the foundation of all contrast agents currently in use. Gadolinium affects the way in which tissues respond to magnetization, resulting in better visualization of structures when compared to un-enhanced studies. Unlike ionic (i.e., iodine-based) contrast agents used in conventional contrast angiography (CA), allergic reactions to gadolinium are extremely rare. Additionally, gadolinium does not cause the kidney failure occasionally seen with ionic contrast agents. Digital subtraction angiography (DSA) is a computer-augmented form of CA that obtains digital blood flow images as contrast agent courses through a blood vessel. The computer "subtracts" bone and other tissue from the image, thereby improving visualization of blood vessels. Physicians elect to use a specific MRA or CA technique based upon clinical information from each patient.

In a National Coverage Analysis Decision Memorandum issued on April 15, 2003, CMS reviewed scientific and clinical literature on MRA, and set forth its basis for the following coverage policy. Below are the only indications for which Medicare coverage is allowed for MRA.

B. Nationally Covered Indications

1. Head and Neck

Studies have proven that MRA is effective for evaluating flow in internal carotid vessels of the head and neck. However, not all potential applications of MRA have been shown to be reasonable and necessary. All of the following criteria must apply in order for Medicare to provide coverage for MRA of the head and neck:

a. MRA is used to evaluate the carotid arteries, the circle of Willis, the anterior, middle or posterior cerebral arteries, the vertebral or basilar arteries or the venous sinuses;

b. MRA is used to verify the need for anticipated surgery for conditions that include, but are not limited to, tumor, aneurysms, vascular malformations, vascular occlusion, or thrombosis. Within this broad category of disorders, medical necessity is the underlying determinant of the need for an MRA. Because MRA and CA perform the same diagnostic function, the medical records should clearly justify and demonstrate the existence of medical necessity*; and*

c. MRA and contrast angiography (CA) are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests.

2. Peripheral Arteries of Lower Extremities

Studies have proven that MRA of peripheral arteries is useful in determining the presence and extent of peripheral vascular disease in lower extremities. This procedure is non-invasive and has been shown to find occult vessels in some patients for which those vessels were not apparent when CA was performed. Medicare will cover either MRA *or* CA to evaluate peripheral arteries of the lower extremities. However, both MRA and CA may be useful is some cases, such as:

a. A patient has had CA and this test was unable to identify a viable run-off vessel for bypass. When exploratory surgery is not believed to be a reasonable medical course of action for this patient, MRA may be performed to identify the viable runoff vessel*; or*

b. A patient has had MRA, but the results are inconclusive.

3. Abdomen and Pelvis

a. Pre-operative Evaluation of Patients Undergoing Elective Abdominal Aortic Aneurysm (AAA) Repair (Effective July 1, 1999)

The MRA is covered for pre-operative evaluation of patients undergoing elective AAA repair if the scientific evidence reveals MRA is considered comparable to CA in determining the extent of AAA, as well as *in* evaluating aortoiliac occlusion disease and renal artery pathology that may be necessary in the surgical planning of AAA repair.

These studies also reveal that MRA could provide a net benefit to the patient. If preoperative CA is avoided, then patients are not exposed to the risks associated with invasive procedures, contrast media, end-organ damage, or arterial injury.

b. Imaging the Renal Arteries and the Aortoiliac Arteries in the Absence of AAA or Aortic Dissection (Effective July 1, 2003)

The MRA coverage is expanded to include imaging the renal arteries and the aortoiliac arteries in the absence of AAA or aortic dissection. MRA should be obtained in those circumstances in which using MRA is expected to avoid obtaining CA, when physician history, physical examination, and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. However, CA may be ordered after obtaining the results of an MRA in those rare instances where medical necessity is demonstrated.

4. Chest

a. Diagnosis of Pulmonary Embolism

Current scientific data has shown that diagnostic pulmonary MRAs are improving due to recent developments such as faster imaging capabilities and gadolinium-enhancement. However, these advances in MRA are not significant enough to warrant replacement of pulmonary angiography in the diagnosis of pulmonary embolism for patients who have no contraindication to receiving intravenous iodinated contrast material. Patients who are allergic to iodinated contrast material face a high risk of developing complications if they undergo pulmonary angiography or computed tomography angiography. Therefore, Medicare will cover MRA of the chest for diagnosing a suspected pulmonary embolism only when it is contraindicated for the patient to receive intravascular iodinated contrast material.

b. Evaluation of Thoracic Aortic Dissection and Aneurysm

Studies have shown that MRA of the chest has a high level of diagnostic accuracy for pre-operative and post-operative evaluation of aortic dissection of aneurysm. Depending on the clinical presentation, MRA is used as an alternative to other non-invasive imaging technologies, such as transesophageal echocardiography and CT. Generally, Medicare will provide coverage only for MRA or for CA when used as a diagnostic test. However, if both MRA and CA of the chest are used, the physician must demonstrate the medical need for performing these tests.

While the intent of this policy is to provide reimbursement for either MRA or CA, CMS is also allowing flexibility for physicians to make appropriate decisions concerning the use of these tests based on the needs of individual patients. CMS anticipates, however, low utilization of the combined use of MRA and CA. As a result, CMS encourages contractors to monitor the use of these tests and, where indicated, requires evidence of the need to perform both MRA and CA.

C. Nationally Noncovered Indications

All other uses of MRA for which CMS has not specifically indicated coverage continue to be noncovered.

D. Other

Not applicable.

(This NCD last reviewed September 2004.)

220.4 - Mammograms

(Rev. 1, 10-03-03)
CIM 50-21

A diagnostic mammography is a radiologic procedure furnished to a man or woman with signs and symptoms of breast disease, or a personal history of breast cancer, or a personal history of biopsy – proven benign breast disease, and includes a physician's interpretation of the results of the procedure. A diagnostic mammography is a covered service if it is ordered by a doctor of medicine or osteopathy as defined in §1861 (r) (1) of the Act. A screening mammography is a radiologic procedure furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure. A screening mammography has limitations as it must be, at a minimum a two-view exposure (cranio-caudal and a medial lateral oblique view) of each breast. Payment may not be made for a screening mammography performed on a woman under age 35. Payment may be made for only one screening mammography performed on a woman over age 34, but under age 40. For an asymptomatic woman over age 39, payment may be made for a screening mammography performed after at least 11 months have passed following the month in which the last screening mammography was performed.

A radiological mammogram is a covered diagnostic test under the following conditions:

- A patient has distinct signs and symptoms for which a mammogram is indicated;
- A patient has a history of breast cancer; or
- A patient is asymptomatic but, on the basis of the patient's history and other factors the physician considers significant, the physician's judgment is that a mammogram is appropriate.

Use of mammograms in routine screening of: (1) asymptomatic women aged 50 and over, and (2) asymptomatic women aged 40 or over whose mothers or sisters have had the disease, is considered medically appropriate, but would not be covered for Medicare purposes.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §80.

The Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §50

220.5 - Ultrasound Diagnostic Procedures

(Rev. 1, 10-03-03)
CIM 50-7

Coverage

Ultrasound diagnostic procedures utilizing low energy sound waves are being widely employed to determine the composition and contours of nearly all body tissues except bone and air-filled spaces. This technique permits noninvasive visualization of even the deepest structures in the body. The use of the ultrasound technique is sufficiently developed that it can be considered essential to good patient care in diagnosing a wide variety of conditions.

Ultrasound diagnostic procedures are listed below and are divided into two categories. Medicare coverage is extended to the procedures listed in Category I. Periodic claims review by the intermediary's medical consultants should be conducted to insure that the techniques are medically appropriate and the general indications specified in these categories are met.

Techniques in Category II are considered experimental and should not be covered at this time.

Category I - (Clinically effective, usually part of initial patient evaluation, may be an adjunct to radiologic and nuclear medicine diagnostic technique)

- Echoencephalography, (Diencephalic Midline) (A-Mode)
- Echoencephalography, Complete (Diencephalic Midline and Ventricular Size)
- Ocular and Orbital Echography (A-Mode)
- Covered procedures include efforts to determine the suitability of aphakic patients for implantation of an artificial lens (pseudophakoi) following cataract surgery.
- Ocular and Orbital Sonography (B-Mode)
- Echocardiography, Pericardial Effusion (M-Mode)
- Pericardiocentesis, by Ultrasonic Guidance
- Echocardiography, Cardiac Valve(s) (M-Mode)
- Echocardiography, Complete (M-Mode)
- Echocardiography, limited (e.g., follow-up or limited study) (M-Mode)
- Pleural Effusion Echography

- Thoracentesis, by Ultrasonic Guidance
- Abdominal Sonography, complete survey study (B-Scan)
- Abdominal Sonography, limited (e.g., follow-up or limited study) (B-Scan)
- Abdominal sonography is not synonymous with ultrasound examination of individual organs.
- Renal Cyst Aspiration, by Ultrasonic Guidance
- Renal Biopsy, by Ultrasonic Guidance
- Pancreas Sonography (B-Scan)
- Pancreatic sonography has proven effective in diagnosing pseudocysts.
- Spleen Sonography (B-Scan)
- Abdominal Aorta Echography (A-Mode)
- Abdominal Aorta Sonography (B-Scan)
- Retroperitoneal Sonography (B-Scan)
- Retroperitoneal sonography does not include planning of fields for radiation therapy.
- Urinary Bladder Sonography (B-Scan)
- Urinary bladder sonography does not include staging of bladder tumors.
- Pregnancy Diagnosis sonography (B-Scan)
- Fetal Age Determination (Biparietal Diameter) Sonography (B-Scan)
- Fetal Growth Rate Sonography (B-Scan)
- Placenta Localization Sonography (B-Scan)
- Pregnancy Sonography, Complete (B-Scan)
- Molar Pregnancy Diagnosis Sonography (B-Scan)
- Ectopic Pregnancy Diagnosis sonography (B-Scan)
- Passive Testing (Antepartum Monitoring of Fetal Heart Rate In the Resting Fetus)
- Intrauterine Contraceptive Device Sonography (B-Scan)
- Pelvic Mass Diagnosis Sonography (B-Scan)
- Amniocentesis, by Ultrasonic Guidance
- Arterial Flow Study, Peripheral (Doppler)
- Venous Flow Study, Peripheral (Doppler)
- Arterial Aneurysm, Peripheral (B-Scan)
- Radiation Therapy Planning Sonography (B-Scan)
- Thyroid Echography (A-Mode)
- Thyroid Sonography (B-Scan)
- Breast Echography (A-Mode)
- Breast Sonography (B-Scan)
- Hepatic Sonography (B-Scan)
- Gallbladder Sonography
- Renal Sonography
- Two-Dimensional Echocardiography (B-Mode)

Category II - (Clinical reliability and efficacy not proven)

- B-Scan for atherosclerotic narrowing of peripheral arteries.

- Monitoring of cardiac output (Doppler)

In view of the rapid changes in the field of ultrasound diagnosis, uses for ultrasound diagnostic procedures other than those listed under Categories I and II should be carefully reviewed before payment. Medical justification may be required. When appropriate, new uses for ultrasound diagnostic procedures should be forwarded to the Bureau of Eligibility, Reimbursement and Mammography , CMS, so that revisions may be made in the coverage policy when appropriate.

Cross refererence: §20.17.

220.6 - Dementia and Neurodegenerative Diseases (Effective September 15, 2004)

(Rev. 24, Issued: 10-01-04, Effective: 09-15-04, Implementation: 10-04-2004)

A. General

Medicare covers FDG-PET scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Specific requirements for each indication are clarified below:

B. Nationally Covered Indications

1. FDG-PET Requirements for Coverage in the Differential Diagnosis of AD and FTD:

An FDG-PET scan is considered reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.

The following additional conditions must be met before an FDG-PET scan will be covered:

a. The patient's onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD;

b. The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the

patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);

c. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;

d. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through FDG-PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;

e. The FDG-PET scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;

f. A brain single photon emission computed tomography (SPECT) or FDG-PET scan has not been obtained for the same indication.

(The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or FDG-PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, an FDG-PET scan may be covered after one year has passed from the time the first SPECT or FDG-PET scan was performed.)

g. The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an FDG-PET scan by ensuring that the following information has been collected and is maintained in the beneficiary medical record:

- ***Date of onset of symptoms;***
- ***Diagnosis of clinical syndrome (normal aging; mild cognitive impairment or MCI; mild, moderate or severe dementia);***
- ***Mini mental status exam (MMSE) or similar test score;***
- ***Presumptive cause (possible, probable, uncertain AD);***
- ***Any neuropsychological testing performed;***
- ***Results of any structural imaging (MRI or CT) performed;***
- ***Relevant laboratory tests (B12, thyroid hormone); and,***
- ***Number and name of prescribed medications.***

The billing provider must furnish a copy of the FDG-PET scan result for use by CMS and its contractors upon request. These verification requirements are consistent with federal requirements set forth in 42 Code of Federal Regulations section 410.32 generally for diagnostic x-ray tests, diagnostic laboratory tests, and other tests. In summary, section 410.32 requires the billing physician and the referring physician to maintain information in the medical record of each patient to demonstrate medical necessity [410.32(d) (2)] and submit the information demonstrating medical necessity to CMS and/or its agents upon request [410.32(d)(3)(I)] (OMB number 0938-0685).

2. FDG-PET Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of FDG-PET in the Diagnosis, and Treatment of Neurodegenerative Dementing Diseases

An FDG-PET scan is considered reasonable and necessary in patients with mild cognitive impairment or early dementia (in clinical circumstances other than those specified in subparagraph 1) only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the FDG-PET scan.

The clinical trial must compare patients who do and do not receive an FDG-PET scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:

- ***a. Written protocol on file;***
- ***b. Institutional Review Board review and approval;***
- ***c. Scientific review and approval by two or more qualified individuals who are not part of the research team; and,***
- ***d. Certification that investigators have not been disqualified.***

C. <u>Nationally Noncovered Indications</u>

All other uses of FDG-PET for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease) for which CMS has not specifically indicated coverage continue to be noncovered.

D. <u>Other</u>

Not applicable.

(This NCD last reviewed September 2004.)

220.7 - Xenon Scan

(Rev. 1, 10-03-03)
CIM 50-27

Program payment may be made for this diagnostic procedure which involves perfusion lung imaging with 133 xenon. However, review for evidence of abuse which might

include absence of reasonable indications, inappropriate sequence, or excessive number or kinds of procedures used in the care of individual patients.

220.8 - Nuclear Radiology Procedure

(Rev. 1, 10-03-03)
CIM 50-30

Nuclear radiology procedures, including nuclear examinations performed with mobile radiological equipment, are covered if reasonable and necessary for the individual patient. Although these procedures may not be widely used, they are generally accepted. Review claims for these procedures for evidence of abuse that might include absence of reasonable indications, inappropriate sequence, or excessive number or kinds of procedures used in the care of individual patients.

220.9 - Digital Subtraction Angiography

(Rev. 1, 10-03-03)
CIM 50-43

Digital subtraction angiography (DSA) is a diagnostic imaging technique that applies computer technology to fluoroscopy for the purpose of visualizing the same vascular structures observable with conventional angiography. Since the radiographic contrast material can be injected into a vein rather than an artery, the procedure reduces the risk to patients, and can be done on an outpatient basis.

Contractors should be alert to possible increases in utilization of DSA over conventional angiographic procedures, as well as to the fact that ordinarily patients should not require inpatient hospitalization solely to perform the procedure.

Payment for DSA should not exceed, and may be less than, that being paid for conventional angiographic techniques.

220.10 - Portable Hand-Held X-Ray Instrument

(Rev. 1, 10-03-03)
CIM 50-48

This low intensity x-ray imaging device is a light weight portable hand-held instrument using a low level isotope as its penetrating energy source. It can picture any part of the human anatomy that can be inserted in the space between the energy source and the viewing mechanism. The device can be useful in making an immediate diagnosis in the following settings: isolated areas, accident scenes, sports events and emergency rooms. It is also useful in the following instances where fluoroscopy would ordinarily be used: localization of foreign bodies, selected surgical procedures and the evaluation of premature or low birth weight infants. The use of the portable hand-held x-ray instrument as an imaging device is covered under Medicare. It should be reimbursed as part of the physicians' professional service, and no additional charge should be allowed.

220.11 - Thermography

(Rev. 1, 10-03-03)
CIM 50-5

Thermography is the measurement of self-emanating infrared radiation that reveals temperature variations at the surface of the body. The thermographic device senses body temperature and demonstrates areas of differing heat emission by producing brightly colored patterns. Each color represents a specific temperature level. Interpretation of these color patterns according to designated anatomic distribution is thought to aid in diagnosing a vast array of diseases.

Thermography for any indication (including breast lesions which were excluded from Medicare coverage on July 20, 1984) is excluded from Medicare coverage because the available evidence does not support this test as a useful aid in the diagnosis or treatment of illness or injury. Therefore, it is not considered effective. This exclusion was published as a CMS Final Notice in the "Federal Register" on November 20, 1992.

220.12 - Single Photon Emission Computed Tomograph (SPECT)

(Rev. 1, 10-03-03)
CIM 50-58

SPECT acquires information on the concentration of radionuclides introduced into the patient's body. It is useful in the diagnosis of several clinical conditions including:

- Stress fracture
- Spondylosis
- Infection (e.g., discitis)
- Tumor (e.g., osteoid osteoma)
- Analyze blood flow to an organ, as in the case of myocardial viability
- Differentiate ischemic heart disease from dilated cardiomyopathy.

Frequency limitations: Contractor discretion.
In the case of myocardial viability, FDG PET may be used following a SPECT that was found to be inconclusive. However, SPECT may not be used following an inconclusive FDG PET performed to evaluate myocardial viability.

220.13 - Percutaneous Image-Guided Breast Biopsy

(Rev. 1, 10-03-03)
CIM 50-59

Percutaneous image-guided breast biopsy is a method of obtaining a breast biopsy through a percutaneous incision by employing image guidance systems. Image guidance systems may be either ultrasound or stereotactic.

The Breast Imaging Reporting and Data System (or BIRADS system) employed by the American College of Radiology provides a standardized lexicon with which radiologists may report their interpretation of a mammogram. The BIRADS grading of mammograms is as follows: Grade I-Negative, Grade II-Benign finding, Grade III-Probably benign, Grade IV-Suspicious abnormality, and Grade V-Highly suggestive of malignant neoplasm.

A - Nonpalpable Breast Lesions

Effective January 1, 2003, Medicare covers percutaneous image-guided breast biopsy using stereotactic or ultrasound imaging for a radiographic abnormality that is nonpalpable and is graded as a BIRADS III, IV, or V.

B - Palpable Breast Lesions

Effective January 1, 2003, Medicare covers percutaneous image guided breast biopsy using stereotactic or ultrasound imaging for palpable lesions that are difficult to biopsy using palpation alone. Contractors have the discretion to decide what types of palpable lesions are difficult to biopsy using palpation.

230 - Renal and Genitourinary System - ESRD Services

230.1 - Treatment of Kidney Stones

(Rev. 1, 10-03-03)
CIM 35-81

Traditional approaches for the treatment of kidney stones are the surgical technique nephrectomy (or nephrotomy) and endoscopic treatments via the urethra. In the last few years, several new approaches in the surgical management of upper urinary tract kidney stones have been developed, among them invasive and noninvasive lithotripsy techniques.

In addition to the traditional surgical/endoscopic techniques for the treatment of kidney stones, the following lithotripsy techniques are also covered for services rendered on or after March 15, 1985.

A - Extracorporeal Shock Wave Lithotripsy

Extracorporeal Shock Wave Lithotripsy (ESWL) is a noninvasive method of treating kidney stones using a device called a lithotriptor. The lithotriptor uses shock waves generated outside of the body to break up upper urinary tract stones. It focuses the shock waves specifically on stones under x-ray visualization, pulverizing them by repeated shocks. ESWL is covered under Medicare for use in the treatment of upper urinary tract kidney stones.

B - Percutaneous Lithotripsy

Percutaneous lithotripsy (or nephrolithotomy) is an invasive method of treating kidney stones by using ultrasound, electrohydraulic or mechanical lithotripsy. A probe is inserted through an incision in the skin directly over the kidney and applied to the stone. A form of lithotripsy is then used to fragment the stone. Mechanical or electrohydraulic lithotripsy may be used as an alternative or adjunct to ultrasonic lithotripsy. Percutaneous lithotripsy of kidney stones by ultrasound or by the related techniques of electrohydraulic or mechanical lithotripsy is covered under Medicare.

The following is covered for services rendered on or after January 16, 1988.

C - Transurethral Ureteroscopic Lithotripsy

Transurethral ureteroscopic lithotripsy is a method of fragmenting and removing ureteral and renal stones through a cystoscope. The cystoscope is inserted through the urethra into the bladder. Catheters are passed through the scope into the opening where the ureters enter the bladder. Instruments passed through this opening into the ureters are used to manipulate and ultimately disintegrate stones, using either mechanical crushing, transcystoscopic electrohydraulic shock waves, ultrasound, or laser. Transurethral ureteroscopic lithotripsy for the treatment of urinary tract stones of the kidney or ureter is covered under Medicare.

230.2 - Uroflowmetric Evaluations

(Rev. 1, 10-03-03)
CIM 50-33

Uroflowmetric evaluations (also referred to as urodynamic voiding or urodynamic flow studies) are covered under Medicare for diagnosing various urological dysfunctions, including bladder outlet obstructions.

230.3 - Sterilization

(Rev. 1, 10-03-03)
CIM 35-11

A - Covered Conditions

- Payment may be made only where sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor or removal of diseased ovaries.
- Sterilization of a mentally retarded beneficiary is covered if it is a necessary part of the treatment of an illness or injury, (bilateral oophorectomy), or bilateral orchidectomy in a case of cancer of the prostate. The contractor denies claims when the pathological evidence of the necessity to perform any such procedures to treat an illness or injury is absent; and .

- Monitor such surgeries closely and obtain the information needed to determine whether in fact the surgery was performed as a means of treating an illness or injury or only to achieve sterilization.

B - Noncovered Conditions

- Elective hysterectomy, tubal ligation, and vasectomy, if the stated reason for these procedures is sterilization;
- A sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury within the meaning of §1862(a)(1) of the Act. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant; and sterilization of a mentally retarded person where the purpose is to prevent conception, rather than the treatment of an illness or injury.

230.4 - Diagnosis and Treatment of Impotence

(Rev. 1, 10-03-03)
CIM 35-24

Program payment may be made for diagnosis and treatment of sexual impotence. Impotence is a failure of a body part for which the diagnosis, and frequently the treatment, require medical expertise. Depending on the cause of the condition, treatment may be surgical; e.g., implantation of a penile prosthesis, or nonsurgical; e.g., medical or psychotherapeutic treatment. Since causes and, therefore, appropriate treatment vary, if abuse is suspected it may be necessary to request documentation of appropriateness in individual cases. If treatment is furnished to patients (other than hospital inpatients) in connection with a mental condition, apply the psychiatric service limitation described in the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3.

230.5 - Gravlee Jet Washer

(Rev. 1, 10-03-03)
CIM 50-4

The Gravlee Jet Washer is a sterile, disposable, diagnostic device for detecting endometrial cancer. The use of this device is indicated where the patient exhibits clinical symptoms or signs suggestive of endometrial disease, such as irregular or heavy vaginal bleeding.

Program payment cannot be made for the washer or the related diagnostic services when furnished in connection with the examination of an asymptomatic patient. Payment for routine physical checkups is precluded under the statute. (See §1862(a)(7) of the Act.)

(See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §90).

230.6 - Vabra Aspirator

(Rev. 1, 10-03-03)
CIM 50-10

The VABRA aspirator is a sterile, disposable, vacuum aspirator which is used to collect uterine tissue for study to detect endometrial carcinoma. The use of this device is indicated where the patient exhibits clinical symptoms or signs suggestive of endometrial disease, such as irregular or heavy vaginal bleeding.

Program payment cannot be made for the aspirator or the related diagnostic services when furnished in connection with the examination of an asymptomatic patient. Payment for routine physical checkups is precluded under the statute (§1862(a)(7) of the Act).

Cross-reference:

See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §90, and §230.5 of this manual.

230.7 - Water Purification and Softening Systems Used in Conjunction With Home Dialysis

(Rev. 1, 10-03-03)
CIM 55-1

A - Water Purification Systems

Water used for home dialysis should be chemically free of heavy trace metals and/or organic contaminants that could be hazardous to the patient. It should also be as free of bacteria as possible but need not be biologically sterile. Since the characteristics of natural water supplies in most areas of the country are such that some type of water purification system is needed, such a system used in conjunction with a home dialysis (either peritoneal or hemodialysis) unit is covered under Medicare.

There are two types of water purification systems that will satisfy these requirements:

- Deionization - The removal of organic substances, mineral salts of magnesium and calcium (causing hardness), compounds of fluoride and chloride from tap water using the process of filtration and ion exchange; or

- Reverse Osmosis - The process used to remove impurities from tap water utilizing pressure to force water through a porous membrane.

Use of both a deionization unit and reverse osmosis unit in series, theoretically to provide the advantages of both systems, has been determined medically unnecessary since either system can provide water which is both chemically and bacteriologically pure enough for acceptable use in home dialysis. In addition, spare deionization tanks are not covered

since they are essentially a precautionary supply rather than a current requirement for treatment of the patient.

Activated carbon filters used as a component of water purification systems to remove unsafe concentrations of chlorine and chloramines are covered when prescribed by a physician.

B - Water Softening System

Except as indicated below, a water softening system used in conjunction with home dialysis is excluded from coverage under Medicare as not being reasonable and necessary within the meaning of §1862(a)(1) of the Act. Such a system, in conjunction with a home dialysis unit, does not adequately remove the hazardous heavy metal contaminants (such as arsenic) which may be present in trace amounts.

A water softening system may be covered when used to pretreat water to be purified by a reverse osmosis (RO) unit for home dialysis where:
The manufacturer of the RO unit has set standards for the quality of water entering the RO (e.g., the water to be purified by the RO must be of a certain quality if the unit is to perform as intended);

The patients water is demonstrated to be of a lesser quality than required; and

The softener is used only to soften water entering the RO unit, and thus, used only for dialysis. (The softener need not actually be built into the RO unit, but must be an integral part of the dialysis system.)

C - Developing Need When a Water Softening System is Replaced with a Water

Purification Unit in an Existing Home Dialysis System

The medical necessity of water purification units must be care fully developed when they replace water softening systems in existing home dialysis systems. A purification system may be ordered under these circumstances for a number of reasons. For example, changes in the medical community's opinions regarding the quality of water necessary for safe dialysis may lead the physician to decide the quality of water previously used should be improved, or the water quality itself may have deteriorated. Patients may have dialyzed using only an existing water softener previous to Medicare ESRD coverage because of inability to pay for a purification system. On the other hand, in some cases, the installation of a purification system is not medically necessary. Thus, when such a case comes to the contractor's attention, the contractor asks the physician to furnish the reason for the changes. Supporting documentation, such as the suppliers recommendations or water analysis, may be required. All such cases should be reviewed by the contractor's medical consultants.

Cross reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §110.

230.8 - Non-Implantable Pelvic Flood Electrical Stimulator

(Rev. 1, 10-03-03)
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.

230.9 - Cryosurgery of Prostate

(Rev. 1, 10-03-03)
CIM 35-96

Cryosurgery of the prostate gland, also known as cryosurgical ablation of the prostate (CSAP), destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland. It is safe and effective, as well as medically necessary and appropriate, as primary treatment for patients with clinically localized prostate cancer, Stages T1-T3.

Cryosurgery of the prostate as a salvage therapy is not covered for any services performed prior to June 30, 2001.

Salvage Cryosurgery Of Prostate After Radiation Failure. Salvage cryosurgery of the prostate for recurrent cancer is medically necessary and appropriate only for those patients with localized disease who:

1 - Have failed a trial of radiation therapy as their primary treatment; and
2 - Meet one of the following conditions: Stage T2B or below, Gleason score < 9, PSA < 8 ng/mL.

Cryosurgery as salvage therapy is therefore not covered under Medicare after failure of other therapies as the primary treatment. Cryosurgery as salvage is only covered after the failure of a trial of radiation therapy, under the conditions noted above.

230.10 - Incontinence Control Devices

(Rev. 1, 10-03-03)
CIM 65-9

A - Mechanical/Hydraulic Incontinence Control Devices

Mechanical/hydraulic incontinence control devices are accepted as safe and effective in the management of urinary incontinence in patients with permanent anatomic and neurologic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. The materials used and the success rate may vary somewhat from device to device. Such a device is covered when its use is reasonable and necessary for the individual patient.

B - Collagen Implant

A collagen implant which is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4-week period.

In male patients, the evaluation must include a complete history and physical examination and a simple cystometrogram to determine that the bladder fills and stores properly. The patient then is asked to stand upright with a full bladder and to cough or otherwise exert abdominal pressure on his bladder. If the patient leaks, the diagnosis of ISD is established.

In female patients, the evaluation must include a complete history and physical examination (including a pelvic exam) and a simple cystometrogram to rule out abnormalities of bladder compliance and abnormalities of urethral support. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H2O, is defined as the intra-abdominal pressure at which leakage occurs from the bladder (around a catheter) when the bladder has been filled with

a minimum of 150 cc fluid. If the patient has an ALLP of less than 100 cm H2O, the diagnosis of ISD is established.

To use a collagen implant, physicians must have urology training in the use of a cystoscope and must complete a collagen implant training program.

Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD:

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H2O or less.

Patients whose incontinence does not improve with five injection procedures (five separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered. Patients who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120. (See §230.8.)

230.11 - Diagnostic Pap Smears

(Rev. 1, 10-03-03)
CIM 50-20

The guide in §190.2 applies.

230.12 - Dimethyl Sulfoxide (DMSO)

(Rev. 1, 10-03-03)
CIM 45-23

DMSO is an industrial solvent produced as a chemical byproduct of paper production from wood pulp. The Food and Drug Administration has determined that the only purpose for which DMSO is safe and effective for humans is in the treatment of the bladder condition, interstitial cystitis. Therefore, the use of DMSO for all other indications is not considered to be reasonable and necessary. Payment may be made for its use only when reasonable and necessary for a patient in the treatment of interstitial cystitis.

230.13 - Peridex CAPD Filter Set

(Rev. 1, 10-03-03)
CIM 55-2

The Peridex Filter Set is used by home continuous ambulatory peritoneal dialysis (CAPD) patients. The Peridex Filter Set is designed to provide sterile filtration during infusion of the dialysis solution in a beneficiary's peritoneal cavity; included in the filter set is a bacterial filter designed to block peritonitis-causing organisms and thus reduce the incidence of peritonitis.

Based upon advice of our medical consultants, CMS has determined that the Peridex CAPD Filter Set cannot be covered at this time by Medicare because it has not yet been shown to be safe and effective in preventing peritonitis.

230.14 - Ultrafiltration Monitor

(Rev. 1, 10-03-03)
CIM 55-3

The Ultrafiltration Monitor is designed to reduce the clinical risks of overfiltration and underfiltration during hemodialysis. Overfiltration is the removal of too much fluid from body tissues and underfiltration is removal of too little fluid.

Covered

Ultrafiltration and ultrafiltration monitoring as a component of hemodialysis has an established and critical role in maintaining the well-being of ESRD patients and is a covered service. The Ultrafiltration Monitor is covered under the Medicare program when it is used to calculate fluid rates for those recipients who present difficult fluid management problems. Determine the medical necessity of this device on a case-by-case basis.

Not Covered

Ultrafiltration, independent of conventional dialysis, is considered experimental, and technology exclusively designed for this purpose is not covered under Medicare.

230.15 - Electrical Continence Aid

(Rev. 1, 10-03-03)
CIM 65-2

Not Covered

An electrical continence aid is a device consisting of a plastic plug, molded into the shape of the patient's anal canal which contains two implanted electrodes that are connected by

a wire to a small portable generator. An electrical current is produced which stimulates the anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

Electrical continence aids are in the experimental stage of development and there is no valid scientific documentation of their effectiveness and safety. Therefore, they are not covered under Medicare since they cannot be considered to be reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by §1862(a)(1) of the Act.

230.16 - Bladder Stimulators (Pacemakers)

(Rev. 1, 10-03-03)
CIM 65-11

Not Covered

There are a number of devices available to induce emptying of the urinary bladder by using electrical current which forces the muscles of the bladder to contract. These devices (commonly known as bladder stimulators or pacemakers) are characterized by the implantation of electrodes in the wall of the bladder, the rectal cones, or the spinal cord. While these treatments may effectively empty the bladder, the issue of safety involving the initiation of infection, erosion, placement, and material selection has not been resolved. Further, some facilities previously using electronic emptying have stopped using this method due to the pain experienced by the patient.

The use of spinal cord electrical stimulators, rectal electrical stimulators, and bladder wall stimulators is not considered reasonable and necessary. Therefore, no program payment may be made for these devices or for their implant.

230.17 - Urinary Drainage Bags

(Rev. 1, 10-03-03)
CIM 65-17

Urinary collection and retention system are covered as prosthetic devices that replace bladder function in the case of permanent urinary incontinence. Urinary drainage bags that can be used either as bedside or leg drainage bags may be either multi-use or single use systems. Both the multi-use and the single use bags have a system that prevents urine backflow. However, the single use system is non-drainable. There is insufficient evidence to support the medical necessity of a single use system bag rather than the multi-use bag. Therefore, a single use drainage system is subject to the same coverage parameters as the multi-use drainage bags.

230.18 - Sacral Nerve Stimulation for Urinary Incontinence

(Rev. 1, 10-03-03)
CIM 65-18

Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.

The following limitations for coverage apply to all three indications:

- Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications are excluded.
- Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50 percent or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

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

(Rev. 1, 10-03-03)
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:

- Erthropoietin-resistant anemia (persistent hermatocrit < 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

- Hypertension 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 six 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-resistent 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.

240 - Respiratory System

(Rev. 1, 10-03-03)

240.1 - Lung Volume Reduction Surgery (Reduction Pneumoplasty)

(Rev. 3, 11-04-03)

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with severe emphysema in order to allow the remaining compressed lung to expand, and thus, improve respiratory function.

Covered Indications

Medicare-covered LVRS approaches are limited to bilateral excision of a damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.

1. National Emphysema Treatment Trial (NETT) participants (effective for services performed on or after August 11, 1997):

Medicare provides coverage to those beneficiaries who are participating in the NETT trial for all services integral to the study and for which the Medicare statute does not prohibit coverage.

2. Medicare will only consider LVRS reasonable and necessary when all of the following requirements are met (effective for services performed on or after January 1, 2004):

a. The patient satisfies all the criteria outlined below:

Assessment	**Criteria**
History and physical examination	Consistent with emphysema
	BMI, ≤ 31.1 kg/m^2 (men) or ≤ 32.3 kg/m^2 (women)
	Stable with $\leq$20 mg prednisone (or equivalent) qd
Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema
Pulmonary function (pre-rehabilitation)	Forced expiratory volume in one second (FEV_1) $\leq$ 45% predicted ($\geq$ 15% predicted if age $\geq$70 years)
	Total lung capacity (TLC) $\geq$100% predicted post-bronchodilator
	Residual volume (RV) $\geq$150% predicted post-bronchodilator
Arterial blood gas level (pre-rehabilitation)	PCO_2, $\leq$ 60 mm Hg (PCO_2, $\leq$ 55 mm Hg if 1-mile above sea level)
	PO_2, $\geq$ 45 mm Hg on room air (PO_2, $\geq$ 30 mm Hg if 1-mile above sea level)

Cardiac assessment	Approval for surgery by cardiologist if any of the following are present: Unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF < 45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (> 5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest)
Surgical assessment	Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation
Exercise	Post-rehabilitation 6-min walk of ≥140 m; able to complete 3 min unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)
Consent	Signed consents for screening and rehabilitation
Smoking	Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products)
	Nonsmoking for 4 months prior to initial interview and throughout evaluation for surgery
Preoperative diagnostic and therapeutic program adherence	Must complete assessment for and program of preoperative services in preparation for surgery

b. In addition, the patient must have:

- Severe upper lobe predominant emphysema (as defined by radiologist assessment of upper lobe predominance on CT scan), or
- Severe non-upper lobe emphysema with low exercise capacity.

Patients with low exercise capacity are those whose maximal exercise capacity is at or below 25 watts for women and 40 watts (w) for men after completion of the preoperative therapeutic program in preparation for LVRS. Exercise capacity is measured by incremental, maximal, symptom-limited exercise with a cycle ergometer utilizing 5 or 10 watt/minute ramp on 30% oxygen after 3 minutes of unloaded pedaling.

c. The surgery must be performed at facilities that were identified by the National Heart, Lung, and Blood Institute to meet the thresholds for participation in the NETT, and at sites that have been approved by Medicare as lung transplant facilities. These facilities are listed on our Web site at www.cms.hhs.gov/coverage/lvrsfacility.pdf. The CMS is currently working to develop accreditation standards for facilities to perform LVRS and when implemented, will consider LVRS to be reasonable and necessary only at accredited facilities.

d. The surgery must be preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the NETT and designed to maximize the patient's potential to successfully undergo and recover from surgery. The

program must include a 6- to 10-week series of at least 16, and no more than 20, preoperative sessions, each lasting a minimum of 2 hours. It must also include at least 6, and no more than 10, postoperative sessions, each lasting a minimum of 2 hours, within 8 to 9 weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial and nutritional needs, be consistent with the preoperative and postoperative services provided in the NETT, and arranged, monitored, and performed under the coordination of the facility where the surgery takes place.

Noncovered Indications

1. LVRS is not covered in any of the following clinical circumstances:

    a. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;

    b. The disease is unsuitable for LVRS;

    c. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery;

    d. The patient presents with $FEV_1 \leq 20\%$ of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of $\leq 20\%$ of predicted value (high-risk group identified October 2001 by the NETT); or

    e. The patient satisfies the criteria outlined above in section 2(a), and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above).

2. All other indications for LVRS not otherwise specified remain noncovered.

240.2 - Home Use of Oxygen

(Rev. 1, 10-03-03)
CIM 60-4

A - General

Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6)of the Act) is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D. This section also includes special coverage criteria for portable oxygen systems.

Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection F.

B - Medical Documentation

Initial claims for oxygen services must include a completed Form CMS-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use Form CMS-484 for recertifications. (See the Medicare Program Integrity Manual, Chapter 5, for completion of Form CMS-484.)

The medical and prescription information in section B of Form CMS-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by non-physician clinician or a physician employee, it must be reviewed and the Form CMS-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and
- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the carrier's medical staff should review all claims with oxygen flow rates of more than four liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed Form CMS-484. In addition, the supplier or physician may use the space in section C for written confirmation of additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the noncontinuous use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the carrier in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

Carriers are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in the Medicare Program Integrity Manual, Chapter 5, "Items and Services Having Special DMERC Review Considerations." When indicated, carriers may also request documentation of the results of a repeat arterial blood gas or oximetry study.

NOTE: Section 4152 of OBRA 1990 requires earlier recertification and retesting of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §100.2.3, for certification and retesting schedules.)

C - Laboratory Evidence

Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO_2) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services.

When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines.

This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are, existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the carrier needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed during the patient's hospital stay, the test result obtained closest to, but no earlier than two days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease. Carriers may accept an attending physician's statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a major change in their condition relevant to home use of oxygen. If the carrier has reason to believe that there has been a major change in the patient's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

D - Health Conditions

Coverage is available for patients with significant hypoxemia in the chronic stable state, i.e, not during a period of acute illness or an exacerbation of their underlying disease, if:

1. The attending physician has determined that the patient has a health condition outlined in subsection D.1,
2. The patient meets the blood gas evidence requirements specified in subsection D.3, and
3. The patient has appropriately tried other treatment without complete success. (See subsection B.)

1 - Conditions for Which Oxygen Therapy May Be Covered

- A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or

- Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2 - Conditions for Which Oxygen Therapy Is Not Covered

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;

- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;

- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO_2 improves the oxygenation of tissues with impaired circulation; or

- Terminal illnesses that do not affect the lungs.

3 - Covered Blood Gas Values

If the patient has a condition specified in subsection D.1, the carrier must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below.

(a) - Group I - Except as modified in subsection d, coverage is provided for patients with significant hypoxemia evidenced by any of the following:

- An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken at rest, breathing room air.

- An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO_2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5 percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen ,therefore, would not be covered in this situation.

- An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen

improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

(b) - Group II - Except as modified in subsection d, coverage is available for patients whose arterial PO_2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89 percent, if there is evidence of:

- Dependent edema suggesting congestive heart failure;
- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or
- Erythrocythemia with a hematocrit greater than 56 percent.

(c) - Group III - Except as modified in subsection d, carriers must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO_2 levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90 percent. In order for claims in this category to be reimbursed, the carrier's reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims.

The CMS expects few claims to be approved for coverage in this category.

(d) - Variable Factors That May Affect Blood Gas Values - In reviewing the arterial PO_2 levels and the arterial oxygen saturation percentages specified in subsections D. 3.a, b and c, the carrier's medical staff must take into account variations in oxygen measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

E - Portable Oxygen Systems

A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or (2) to use in addition to a stationary oxygen system. Portable oxygen is not covered when it is provided only as a backup to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- The claim meets the requirements specified in subsections A-D, as appropriate; and
- The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep

F - Respiratory Therapists

Respiratory therapists' services are not covered under the provisions for coverage of oxygen services under the Part B durable medical equipment benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

(See §280.1, and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §110)

240.3 - Heat Treatment, Including the Use of Diathermy and Ultra-Sound for Pulmonary Conditions

(Rev. 1, 10-03-03)
CIM 35-3

Not Covered

There is no physiological rationale or valid scientific documentation of effectiveness of diathermy or ultrasound heat treatments for asthma, bronchitis, or any other pulmonary condition and for such purpose this treatment cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

Cross-reference: §150.5.

240.4 - Continuous Positive Airway Pressure (CPAP)

(Rev. 1, 10-03-03)
CIM 60-17

The CPAP is a noninvasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep which occurs in obstructive sleep apnea (OSA).

The diagnosis of OSA requires documentation of at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6-7 hours of recorded sleep. The use of CPAP is covered under Medicare when used in adult patients with moderate or severe OSA for whom surgery is a likely alternative to CPAP.

Initial claims must be supported by medical documentation (separate documentation where electronic billing is used), such as a prescription written by the patient's attending physician, that specifies:

- A diagnosis of moderate or severe obstructive sleep apnea, and
- Surgery is a likely alternative.

- The claim must also certify that the documentation supporting a diagnosis of OSA (described above) is available.

The use of CPAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adult patients with OSA if either of the following criteria using the Apnea-Hyopopnea Index (AHI) are met:

- AHI $\geq$ 15 events per hour, or
- AHI $\geq$ 5 and $\leq$ 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke.

The AHI is equal to the average number of episodes of apnea and hyponea per hour and must be based on a minimum of two hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected).

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent oxygen desaturation.

The polysomnography must be performed in a facility - based sleep study laboratory, and not in the home or in a mobile facility.

Initial claims for CPAP devices must be supported by information contained in the medical record indicating that the patient meets Medicare's stated coverage criteria.

Cross References: §280.1.

240.5 - Intrapulmonary Percussive Ventilator (IPV)

(Rev. 1, 10-03-03)
CIM 60-21

Not Covered

IPV is a mechanized form of chest physical therapy. Instead of a therapist clapping or slapping the patient's chest wall, the IPV delivers mini-bursts (more than 200 per minute) of respiratory gasses to the lungs via a mouthpiece. Its intended purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, peak pressure and delivery rates.

Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting. There are no data to support the effectiveness of the device. Therefore, IPV in the home setting is not covered.

240.6 - Transvenous (Catheter) Pulmonary Embolectomy

(Rev. 1, 10-03-03)
CIM 35-55

Not Covered

Transvenous (catheter) pulmonary embolectomy is a procedure for removing pulmonary emboli by passing a catheter through the femoral vein. It is not covered under Medicare because it is still experimental.

240.7 - Postural Drainage Procedures and Pulmonary Exercises

(Rev. 1, 10-03-03)
CIM 35-15

In most cases, postural drainage procedures and pulmonary exercises can be carried out safely and effectively by nursing personnel. However, in some cases patients may have acute or severe pulmonary conditions involving complex situations in which these procedures or exercises require the knowledge and skills of a physical therapist or a respiratory therapist. Therefore, if the attending physician determines as part of his/her plan of treatment that for the safe and effective administration of such services the procedures or exercises in question need to be performed by a physical therapist, the services of such a therapist constitute covered physical therapy when provided as an inpatient hospital service, extended care service, home health service, or outpatient physical therapy service.

NOTE: Physical therapy furnished in the outpatient department of a hospital is covered under the outpatient physical therapy benefit.

If the attending physician determines that the services should be performed by a respiratory therapist, the services of such a therapist constitute covered respiratory therapy when provided as an inpatient hospital service, outpatient hospital service, or extended care service, assuming that such services are furnished to the skilled nursing facility by a hospital with which the facility has a transfer agreement. Since the services of a respiratory therapist are not covered under the home health benefit, payment may not be made under the home health benefit for visits by a respiratory therapist to a patient's home to provide such services. Postural drainage procedures and pulmonary exercises are also covered when furnished by a physical therapist or a respiratory therapist as incident to a physician's professional service.

Cross references:

The Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20.

The Medicare Benefit Policy Manual, Chapter 7, "Home Health Services," §20.

The Medicare Benefit Policy Manual, Chapter 8, "Coverage of Extended Care (SNF) Services Under Health Insurance," §50.

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.2.

250 - Skin

(Rev. 1, 10-03-03)

250.1 - Treatment of Psoriasis

(Rev. 1, 10-03-03)
CIM 35-66

Psoriasis is a chronic skin disease, for which several conventional methods of treatment have been recognized as covered. These include topical application of steroids or other drugs; ultraviolet light (actinotherapy); and coal tar alone or in combination with ultraviolet B light (Goeckerman treatment).

A newer treatment for psoriasis uses a psoralen derivative drug in combination with ultraviolet A light, known as PUVA. PUVA therapy is covered for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment. The contractor should document this before paying for PUVA therapy.

In addition, reimbursement for PUVA therapy should be limited to amounts paid for other types of photochemotherapy; ordinarily, payment should not be allowed for more than 30 days of treatment, unless improvement is documented.

250.2 - Hemorheograph

(Rev. 1, 10-03-03)
CIM 50-16

The hemorheograph is a diagnostic instrument which is safe and effective for determining the adequacy of skin perfusion prior to the performance of minor surgical procedures on the extremities, including minor podiatric procedures, and as an adjunct to the evaluation of patients suspected of having peripheral vascular disease.

Program payment may be made only for those services employing the hemorheograph which are performed for preoperative and postoperative diagnostic evaluation of suspected peripheral artery disease.

NOTE: This instrument is not a plethysmograph and is not considered as such. A plethysmograph measures and records changes in the size of a body part as modified by the circulation of blood in that part. The hemorheograph, on the

other hand, measures surface blood flow in the skin; it does not measure total blood flow in a digit or limb.

250.3 - Intravenous Immune Globulin for the Treatment of Autoimmune Mucutaneous Blistering Diseases

(Rev. 1, 10-03-03)
CIM 45-31

Intravenous immune globulin (IVIg) is a blood product prepared from the pooled plasma of donors. It has been used to treat a variety of autoimmune diseases, including mucocutaneous blistering diseases. It has fewer side effects than steroids or immunosuppressive agents.

Effective October 1, 2002, IVIg is covered for the treatment of biopsy-proven: (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita for the following patient subpopulations:

- Patients who have failed conventional therapy. Contractors have the discretion to define what constitutes failure of conventional therapy;

- Patients in whom conventional therapy is otherwise contraindicated. conventional therapy; or

- Patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations IVIg therapy would be given along with conventional treatment(s) and the IVIg would be used only until the conventional therapy could take effect.

In addition, IVIg for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy. Contractors have the discretion to decide what constitutes short-term therapy.

HCPCS code pending	**Long description pending**

250.4 - Treatment of Actinic Keratosis

(Rev. 1, 10-03-03)
CIM 35-101

Actinic keratoses (AKs), also known as solar keratoses, are common, sun-induced skin lesions that are confined to the epidermis and have the potential to become a skin cancer. Various options exist for treating AKs. Clinicians should select an appropriate treatment based on the patient's medical history, the lesion's characteristics, and on the patient's preference for a specific treatment. Commonly performed treatments for AKs include cryosurgery with liquid nitrogen, topical drug therapy, and curettage. Less commonly

performed treatments for AK include dermabrasion, excision, chemical peels, laser therapy, and photodynamic therapy (PDT). An alternative approach to treating AKs is to observe the lesions over time and remove them only if they exhibit specific clinical features suggesting possible transformation to invasive squamous cell carcinoma (SCC).

Effective for services performed on and after November 26, 2001, Medicare covers the destruction of actinic keratoses without restrictions based on lesion or patient characteristics.

260 - Transplantation - Solid Organ Transplants

(Rev. 1, 10-03-03)

260.1 - Adult Liver Transplantation

(Rev. 1, 10-03-03)
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 (ICD-9-M 996.82, Complications of Transplanted Organ, Liver 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.

260.2 - Pediatric Liver Transplantation

(Rev. 1, 10-03-03)
CIM 35-53.1

Liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Liver transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application which CMS approves documenting that:
The hospital's pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in the "Federal Register" notice of April 12, 1991;

- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and

- The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric liver transplant patients.

260.3 - Pancreas Transplants (Effective July 1, 1999)

(Rev. 18, Issued 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

CIM 35-82

A. General

Pancreas transplantation is performed to induce an insulin-independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

Medicare has had a long-standing policy of not covering pancreas transplantation, as the safety and effectiveness of the procedure had not been demonstrated. The Office of Health Technology Assessment performed an assessment of pancreas-kidney transplantation in 1994. It found reasonable graft survival outcomes for patients receiving either simultaneous pancreas-kidney transplantation or pancreas-after-kidney transplantation.

B. Nationally Covered Indications

CMS determines that whole organ pancreas transplantation will be nationally covered by Medicare only when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy will begin with the date of discharge from the inpatient stay for the pancreas transplant.

C. Nationally Noncovered Indications

CMS determines that the following procedures are not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:

1. Pancreas transplantation for diabetic patients who have not experienced end-stage renal failure secondary to diabetes.

2. Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the NCD Manual)).

D. Other

Not applicable.

(This NCD last reviewed July 2004.)

260.3.1 - Islet Cell Transplantation in the Context of A Clinical Trial (Effective October 1, 2004)

(Rev. 18, Issued 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

A. General

As a result of section 733 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173), The Secretary of the Department of Health and Human Services, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation that includes Medicare beneficiaries.

The transplant is performed on patients with Type I diabetes. A typical islet cell transplant requires over 500,000 islet cells, but varies depending on the recipient's weight. One of the desired patient outcomes is insulin independence. Elimination of clinically significant hypoglycemia episodes and improved glucose control are other important patient outcomes

One or more pancreata are obtained from donor(s). The islets must be removed within hours after the recovery of the donor pancreas to ensure viability. The islet cells are transplanted by injection into the portal vein of the recipient either using direct visualization, guided ultrasound or percutaneously. The islet cell transplant may be performed alone, in combination with a kidney transplant, or after a kidney transplant. Islet recipients require immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care is necessary for each trial participant.

B. Nationally Covered Indications

Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial(s). The term `routine costs' means reasonable and necessary routine patient care costs, including immunosuppressive drugs and other follow-up care, as defined in section 310.1 of the NCD Manual.

Specifically, Medicare will cover transplantation of pancreatic islet cells, the insulin producing cells of the pancreas. Coverage will include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants.

C. Nationally Noncovered Indications

Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial continues to be noncovered.

D. Other

Not applicable.

(This NCD last reviewed July 2004.)

260.4 - Reserved
(Rev. 1, 10-03-03)

260.5 - Intestinal and Multi-Visceral Transplantation
(Rev. 1, 10-03-03)
CIM 35-104

Intestinal and Multi-Visceral Transplantation

Effective for services performed on and after April 1, 2001, Medicare covers intestinal and multi-visceral transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure. Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. It may be associated with both mortality and profound morbidity. Multi-visceral transplantation includes organs in the digestive system (stomach, duodenum, pancreas, liver and intestine).

The evidence supports the fact that aged patients generally do not survive as well as younger patients receiving intestinal transplantation. Nonetheless, some older patients who are free from other contraindications have received the procedure and are progressing well, as evidenced by the United Network for Organ Sharing (UNOS) data. Thus, it is not appropriate to include specific exclusions from coverage, such as an age limitation, in the national coverage policy.

This procedure is covered only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria.
Failed TPN

TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. TPN failure includes the following:

- Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.

- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, Superior Vena Cava syndrome, or chronic venous insufficiency.

- Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure.

- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreatobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

Approved Transplant Facilities

Intestinal transplantation is covered by Medicare if performed in an approved facility. The criteria for approval of centers will be based on a volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent using the Kaplan-Meier technique.

More specific criteria can be found at:
http://cms.hhs.gov/providers/transplant/default.asp.

260.6 - Dental Examination Prior to Kidney Transplantation

(Rev. 1, 10-03-03)
CIM 50-26

Despite the "dental services exclusion" in §1862(a)(12) of the Act (see the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §140;), an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery is a covered service. This is because the purpose of the examination is not for the care of the teeth or structures directly supporting the teeth. Rather, the examination is for the identification, prior to a complex surgical procedure, of existing medical problems where the increased possibility of infection would not only reduce the chances for successful surgery but would also expose the patient to additional risks in undergoing such surgery.

Such a dental or oral examination would be covered under Part A of the program if performed by a dentist on the hospital's staff, or under Part B if performed by a physician. (When performing a dental or oral examination, a dentist is not recognized as a physician under §1861(r) of the Act.) (See the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, "Definitions," §70.2, and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §150.)

260. 7 - Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine)

(Rev. 1, 10-03-03)
CIM 45-22

The lymphocyte immune globulin preparations are biologic drugs not previously approved or licensed for use in the management of renal allograft rejection. A number of other lymphocyte immune globulin products of equine, lapine, and murine origin are currently under investigation for their potential usefulness in controlling allograft rejections in human transplantation. These biologic drugs are viewed as adjunctive to traditional immunosuppressive products such as steroids and anti-metabolic drugs. At present, lymphocyte immune globulin preparations are not recommended to replace conventional immunosuppressive drugs, but to supplement them and to be used as alternatives to elevated or accelerated dosing with conventional immunosuppressive agents.

The FDA has approved one lymphocyte immune globulin preparation for marketing, lymphocyte immune globulin, anti-thymocyte globulin (equine). This drug is indicated for the management of allograft rejection episodes in renal transplantation. It is covered under Medicare when used for this purpose. Other forms of lymphocyte globulin preparation which the FDA approves for this indication in the future may be covered under Medicare.

260.8 - Reserved

(Rev. 1, 10-03-03)
Reserved

260.9 - Heart Transplants

(Rev. 1, 10-03-03)
CIM 35-87

A - General

Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. (See CMS Ruling 87-1.)

B - Exceptions

In certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than two years, and applications from consortia will not be approved.

Although consortium arrangements will not be approved for payment of Medicare heart transplants, consideration will be given to applications from heart transplant facilities that consist of more than one hospital where all of the following conditions exist:
The hospitals are under the common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally-constituted medical research institute; and

The hospitals share resources by routinely using the same personnel or services in their transplant programs. The sharing of resources must be supported by the submission of operative notes or other information that documents the routine use of the same personnel and services in all of the individual hospitals. At a minimum, shared resources means:

- The individual members of the transplant team, consisting of the cardiac transplant surgeons, cardiologists and pathologists, must practice in all the hospitals and it can be documented that they otherwise function as members of the transplant team; and

- The same organ procurement organization, immunology, and tissue-typing services must be used by all the hospitals; and

- The hospitals submit, in the manner required (Kaplan-Meier method) their individual and pooled experience and survival data; and

- The hospitals otherwise meet the remaining Medicare criteria for heart transplant facilities; that is, the criteria regarding patient selection, patient management, program commitment, etc.

C - Pediatric Hospitals

Cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application whichCMS approves as documenting that:

- The hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in CMS Ruling 87-1;

- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and

- The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

D - Follow-Up Care

Follow-up care required as a result of a covered heart 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 a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §180.)

E - Immunosuppressive Drugs

See the Medicare Claims Processing Manuals, Chapter 17, "Drugs and Biologicals," §§80.3.1 and, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §120.1.

F - Artificial Hearts

Medicare does not cover the use of artificial hearts as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant (often referred to as a "bridge to transplant"). Medicare does cover a ventricular assist device (VAD) when used in conjunction with specific criteria listed in §20.9.

270 - Wound Treatment

(Rev. 1, 10-03-03)

270.1 - Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds – (Effective July 1, 2004)

(Rev 7, 03-19-04)

Electrical stimulation (ES) and electromagnetic therapy have been used or studied for many different applications, one of which is accelerating wound healing. ES for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy uses a pulsed magnetic field to induce current. CMS was asked to reconsider its national noncoverage determination for electromagnetic therapy. After thorough review, CMS determined that the results from the use of electromagnetic therapy for the treatment of wounds were similar to the results from the use of ES. Therefore, effective July 1, 2004, Medicare will cover electromagnetic therapy for the same settings and conditions for which ES is covered. This means Medicare will allow either one covered ES therapy or one covered electromagnetic therapy for the treatment of wounds.

A. Nationally Covered Indications

The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies, and will only be covered for chronic Stage III or Stage IV pressure

ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES or electromagnetic therapy will be covered only after appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute.

Standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours), off-loading of pressure and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of a compression system for patients with venous ulcers.

Measurable signs of improved healing include: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue. ES or electromagnetic therapy must be discontinued when the wound demonstrates 100% epitheliliazed wound bed.

ES and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs ES or electromagnetic therapy, the practitioner must evaluate the wound and contact the treating physician if the wound worsens. If ES or electromagnetic therapy is being used, wounds must be evaluated at least monthly by the treating physician.

B. Nationally Noncovered Indications

1. ES and electromagnetic therapy will not be covered as an initial treatment modality.

2. Continued treatment with ES or electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

3. Unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

C. Other

All other uses of ES and electromagnetic therapy not otherwise specified for the treatment of wounds remain at local contractor discretion.

270.1.1 - Electrical Stimulation for the Treatment of Wounds

(Rev. 1, 10-03-03)
CIM 35-102

Covered

Electrical stimulation (ES) for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. ES for the treatment of wounds will only be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers, Effective for services on and after April 1, 2003. All other uses of electrical stimulation for treatment of wounds are noncovered. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES will not be covered as an initial treatment modality.

The use of ES for the treatment of wounds is considered an adjuctive therapy. ES will be covered only after appropriate standard wound therapy has been tried for at least 30-days and there are no measurable signs of healing. This 30-day period can begin while the wound is acute. Measurable signs of improved healing include a decrease in wound size, either surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes; optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every two hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers; and the use of a compression system for patients with venous ulcers.

Continued treatment with ES is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. ES must be discontinued when the wound demonstrated 100 percent epithelialized wound bed.

Any form of electromagnetic therapy for the treatment of chronic wounds will not be covered.

This service can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When physician, physical therapist, or a clinician incident to a physician, performs ES, that practitioner must evaluate the wound and contact the treating physician if the wound worsens. If ES is being used, wounds must be evaluated at least monthly by the treating physician.

Unsupervised use of ES for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

270.2 - Noncontact Normothermic Wound Therapy (NNWT)

(Rev. 1, 10-03-03)
CIM 60-25

NNWT is a device reported to promote wound healing by warming a wound to a predetermined temperature. The device consists of a noncontact wound cover into which a flexible, battery powered, infrared heating card is inserted. There is insufficient scientific or clinical evidence to consider this device as reasonable and necessary for the treatment of wounds within the meaning of §1862(a)(1)(A) of the Act and will not be covered by Medicare.

270.3 - Blood-Derived Products for Chronic Non-Healing Wounds - (Effective 07-23-04)

(Rev. 19, Issued, 07-30-04, Effective: 07-23-04, Implementation: 07-23-04)

A. General

Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic non-healing cutaneous wounds that persists for 30 days or longer and fail to properly complete the healing process. Autologous blood derived products for chronic non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products such as Procuren, and more recent products, (2) platelet-rich plasma (PRP). PRP is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, fibrinogen, stem cells, macrophages, and fibroblasts. PRP is used by physicians in clinical settings. PDGF does not contain cells and was previously marketed as a product to be used by patients at home.

In latter 1992, CMS issued a national noncoverage determination for platelet-derived wound healing formulas intended to treat patients with chronic, nonhealing wounds. This decision was based on a lack of sufficient published data to determine safety and efficacy, and a Public Health Service technology assessment.

B. Nationally Covered Indications

Not applicable.

C. Nationally Noncovered Indications

1. Upon reconsideration, the clinical effectiveness of autologous PDGF products continues to not be adequately proven in scientific literature. As the evidence is insufficient to conclude that autologous PDGF in a platelet-poor plasma is reasonable and necessary, it remains noncovered for treatment of chronic, non-healing cutaneous wounds.

2. Additionally, the clinical evidence does not support a benefit in the application of autologous PRP for the treatment of chronic, non-healing cutaneous wounds. In light of the absence of data on the health outcomes of this treatment, CMS determines it is not reasonable and necessary and is therefore nationally noncovered.

D. Other

1. Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion. Becaplermin is approved by the Food and Drug Administration.

2. In accordance with section 310.1 of the National Coverage Determinations Manual, the routine costs in Federally sponsored or approved clinical trials assessing the efficacy of autologous PRP in treating chronic, non-healing cutaneous wounds are covered by Medicare.

(This NCD last reviewed July 2004.)

270.4 - Treatment of Decubitus Ulcers

(Rev. 1, 10-03-03)
CIM 35-31

An accepted procedure for healing decubitus ulcers is to remove dead tissue from the lesions and to keep them clean to promote the growth of new tissue. This may be accomplished by hydrotherapy (whirlpool) treatments. Hydrotherapy (whirlpool) treatment for decubitus ulcers is a covered service under Medicare for patients when treatment is reasonable and necessary. Some other methods of treating decubitus ulcers, the safety and effectiveness of which have not been established, are not covered under the Medicare program. Some examples of these types of treatments are: ultraviolet light, low intensity direct current, topical application of oxygen, and topical dressings with Balsam of Peru in castor oil.

270.5 - Porcine Skin and Gradient Pressure Dressings

(Rev. 1, 10-03-03)
CIM 45-12

Porcine (pig) skin dressings are covered, if reasonable and necessary for the individual patient as an occlusive dressing for burns, donor sites of a homograft, and decubiti and other ulcers.

Gradient pressure dressings are Jobst elasticized heavy duty dressings used to reduce hypertrophic scarring and joint contractures following burn injury. They are covered when used for that purpose.

280 - Medical and Surgical Supplies
(Rev. 1, 10-03-03)

280.1 - Durable Medical Equipment Reference List
(Rev. 1, 10-03-03)
CIM 60-9

The durable medical equipment (DME) list which follows is designed to facilitate the contractor's processing of DME claims. This section is designed to be used as a quick reference tool for determining the coverage status of certain pieces of DME and especially for those items which are commonly referred to by both brand and generic names. The information contained herein is applicable (where appropriate) to all DME coverage determinations discussed in the DME portion of this manual. The list is organized into two columns. The first column lists alphabetically various generic categories of equipment on which national coverage decisions have been made by CMS; and the second column notes the coverage status of each equipment category.

In the case of equipment categories that have been determined by CMS to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. With respect to equipment categories that cannot be covered as DME, the list includes a brief explanation of why the equipment is not covered. This DME list will be updated periodically to reflect any additional national coverage decisions that CMS may make with regard to other categories of equipment.

When the contractor receives a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed, the contractor has the authority and responsibility for deciding whether those items are covered under the DME benefit.

These decisions must be made by each contractor based on the advice of its medical consultants, taking into account:

The Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)."

- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended; and

- Whether the item is reasonable and necessary for the individual patient.

The term durable medical equipment (DME) is defined as equipment which:

- Can withstand repeated use; i.e., could normally be rented, and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and
- Is appropriate for use in a patient's home.

Durable Medical Equipment Reference List

Item	Coverage
Air Cleaners	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act).
Air Conditioners	Deny--environmental control equipment; not primarily medical in nature (§1861 (n) of the Act).
Air-Fluidized Bed	(See Air-Fluidized Bed §280.8 of this manual.)
Alternating Pressure Pads, Mattresses and Lambs Wool Pads	Covered if patient has, or is highly susceptible to, decubitus ulcers and the patient's physician has specified that he will be supervising his course of treatment.
Audible/Visible Signal / Pacemaker Monitor	(See Self-Contained Pacemaker Monitor.)
Augmentative Communication Device	(See Speech Generating Devices, §50.1 of this manual.)
Bathtub Lifts	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Bathtub Seats	Deny--comfort or convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act).
Bead Bed	(See §280.8.)
Bed Baths (home type)	Deny--hygienic equipment; not primarily medical in nature ((§1861(n) of the Act).
Bed Lifter (bed elevator)	Deny--not primarily medical in nature ((§1861(n) of the Act).
Bedboards	Deny--not primarily medical in nature ((§1861(n) of the Act).
Bed Pans (autoclavable hospital type)	Covered if patient is bed confined.
Bed Side Rails	(See Hospital Beds, §280.7 of this manual.)
Beds-Lounge (power or manual)	Deny--not a hospital bed; comfort or convenience item; not primarily medical in nature (§1861(n) of the Act).
Beds--Oscillating	Deny--institutional equipment; inappropriate for home use.
Bidet Toilet Seat	(See Toilet Seats.)
Blood Glucose Analyzer--Reflectance Colorimeter	Deny--unsuitable for home use (see §40.2 of this manual).
Blood Glucose Monitor	Covered if patient meets certain conditions (see §40.2 of this manual).
Braille Teaching Texts	Deny--educational equipment; not primarily medical in nature (§1861(n) of the Act).
Canes	Covered if patient's condition impairs ambulation (see §280.2 of this manual).
Carafes	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Catheters	Deny--nonreusable disposable supply (§1861(n) of the Act). (See The Medicare Claims Processing Manual, Chapter 20, Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)

Item	Coverage
Commodes	Covered if patient is confined to bed or room. NOTE: The term "room confined" means that the patient's condition is such that leaving the room is medically contraindicated. The accessibility of bathroom facilities generally would not be a factor in this determination. However, confinement of a patient to his home in a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient's medical condition confines him to a floor of his home and there is no bathroom located on that floor.
Communicator	(See §50.1 of this manual, "Speech Generating Devices.")
Continuous Passive Motion	Continuous passive motion devices are devices Covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the three week period following surgery during which the device is used in the patient's home. There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications.
Continuous Positive Airway Pressure (CPAP)	(See §240.4 of this manual.)
Crutches	Covered if patient's condition impairs Ambulation.
Cushion Lift Power Seat	(See Seat Lifts.)
Dehumidifiers (room or central heating system type)	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act.
Diathermy Machines (standard pulses wave types)	Deny--inappropriate for home use (see §150.5 of this manual).
Digital Electronic Pacemaker Monitor	(See Self-Contained Pacemaker Monitor.)
Disposable Sheets and Bags	Deny--nonreusable disposable supplies (§1861(n) of the Act)
Elastic Stockings	Deny--nonreusable supply; not rental-type items (§1861(n) of the Act) (See §270.5 of this manual)
Electric Air Cleaners	Deny--(See Air Cleaners.) (§1861(n) of the Act).
Electric Hospital Beds	(See Hospital Beds §280.7 of this manual.)
Electrical Stimulation for Wounds	Deny--inappropriate for home use. (See §270.1 of this manual)
Electrostatic Machines	Deny--(See Air Cleaners and Air Conditioners.) (§1861(n) of the Act).
Elevators	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Emesis Basins	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Esophageal Dilator	Deny--physician instrument; inappropriate for patient use.

Item	Coverage
Exercise Equipment	Deny--not primarily medical in nature (§1861(n) of the Act).
Fabric Supports	Deny--nonreusable supplies; not rental-type it (§1861(n) of the Act).
Face Masks (oxygen)	Covered if oxygen is Covered. (See §240.2 of this manual.)
Face Masks (surgical)	Deny--nonreusable disposable items (§1861(n) of the Act)
Flowmeter	(See Medical Oxygen Regulators.) (See §240.2 of this manual.)
Fluidic Breathing Assister	(See Intermittent Positive Pressure Breathing Machines.)
Fomentation Device	(See Heating Pads.)
Gel Flotation Pads and Mattresses	(See Alternating Pressure Pads and Mattresses.)
Grab Bars	Deny--self-help device; not primarily medical in nature (§1861(n) of the Act).
Heat and Massage Foam Cushion Pad	Deny--not primarily medical in nature; personal comfort item (§1861(n) and 1862(a)(6) of the Act).
Heating and Cooling Plants	Deny--environmental control equipment not primary; medical in nature (§1861(n) of the Act).
Heating Pads	Covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heating pad is therapeutically effective.
Heat Lamps	Covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heat lamp is therapeutically effective.
Hospital Beds	(See §280.7 of this manual.)
Hot Packs	(See Heating Pads.)
Humidifiers (oxygen)	(See Oxygen Humidifiers.)
Humidifiers (room or central heating system types)	Deny--environmental control equipment; not medical in nature (§1861(n) of the Act).
Hydraulic Lift	(See Patient Lifts.)
Incontinent Pads	Deny--nonreusable supply; hygienic item (§1861(n) of the Act).
Infusion Pumps	For external and implantable pumps, see §40.2. If the pump is used with an enteral or parenteral nutritional therapy system, see §180.2 for special coverage rules.
Injectors (hypodermic jet	Deny--not covered self-administered drug supply;pressure powered devices (§1861(s)(2)(A) of the Act) for injection of insulin.
Intermittent Positive Pressure Breathing Machines	Covered if patient's ability to breathe is severely impaired.
Iron Lungs	(See Ventilators.)
Irrigating Kit	Deny--nonreusable supply; hygienic equipment (§1861(n) of the Act).
Lambs Wool Pads	(See Alternating Pressure Pads, Mattresses, and Lamb Wool Pads)
Leotards	Deny--(See Pressure Leotards.) (§1861(n) of the Act).

Item	Coverage
Lymphedema Pumps	Covered (See Pneumatic Compression Devices, §280.6 of this manual.)
Massage Devices	Deny--personal comfort items; not primarily medical in nature (§1861(n) and 1862(a)(6) of the Act).
Mattress	Covered only where hospital bed is medically necessary. (Separate Charge for replacement mattress should not be allowed where hospital bed with mattress is rented.) (See §280.7 of this manual.)
Medical Oxygen Regulators	Covered if patient's ability to breathe is severely impaired. (See §240.2 of this manual.)
Mobile Geriatric Chair	(See Rolling Chairs.)
Motorized Wheelchairs	(See Wheelchairs (power operated).)
Muscle Stimulators	Covered for certain conditions. (See §250.4 of this manual.)
Nebulizers	Covered if patient's ability to breathe is severely impaired.
Oscillating Beds	Deny--institutional equipment - inappropriate for home use.
Overbed Tables	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Oxygen	Covered if the oxygen has been prescribed for use in connection with medically necessary durable medical equipment. (See §240.2 of this manual.)
Oxygen Humidifiers	Covered if the oxygen has been prescribed for use in connection with medically necessary durable medical equipment for purposes of moisturizing oxygen. (See §240.2 of this manual.)
Oxygen Regulators (Medical)	(See Medical Oxygen Regulators.)
Oxygen Tents	(See §240.2 of this manual.)
Paraffin Bath Units (Portable)	(See Portable Paraffin Bath Units.)
Paraffin Bath Units (Standard)	Deny--institutional equipment; in appropriate or home use.
Parallel Bars	Deny--support exercise equipment; primarily for institutional use; in the home setting other devices (e.g., a walker) satisfy the patient's need.
Patient Lifts	Covered if contractor's medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest or retard deterioration in his condition.
Percussors	Covered for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient or operator of powered percussor has received appropriate training by a physician or therapist, and no one competent to administer manual therapy is available.
Portable Oxygen Systems	1. Regulated (adjustable Covered under conditions specified in a flow rate). Refer all claims to medical staff for this determination. 2. Preset (flow rate Deny emergency, first-aid, or not

Item	Coverage
	adjustable) precautionary equipment; essentially not therapeutic in nature.
Portable Paraffin Bath Units	Covered when the patient has undergone a successful trial period of paraffin therapy ordered by a physician and the patient's condition is expected to be relieved by long term use of this modality.
Portable Room Heaters	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act).
Portable Whirlpool Pumps	Deny--not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act).
Postural Drainage Boards	Covered if patient has a chronic pulmonary condition.
Preset Portable Oxygen Units	Deny--emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature.
Pressure Leotards	Deny--non-reusable supply, not rental-type item (§1861(n) of the Act).
Pulse Tachometer	Deny--not reasonable or necessary for monitoring pulse of homebound patient with or without a cardiac pacemaker.
Quad-Canes	(See Walkers.)
Raised Toilet Seats	Deny--convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act).
Reflectance Colorimeters	(See Blood Glucose Analyzers.)
Respirators	(See Ventilators.)
Rolling Chairs	Covered if the contractor's medical staff determines that the patient's condition is such that there is a medical need for this item and it has been prescribed by the patient's physician in lieu of a wheelchair. Coverage is limited to those roll-about chairs having casters of at least 5 inches in diameter and specifically designed to meet the needs of ill, injured, or otherwise impaired individuals. Coverage is denied for the wide range of chairs with smaller casters as are found in general use in homes, offices, and institutions for many purposes not related to the care or treatment of ill or injured persons. This type is not primarily medical in nature. (§1861(n) of the Act).
Safety Roller	(See §280.5 of this manual.)
Sauna Baths	Deny--not primarily medical in nature; personal comfort items (§§1861(n) and (1862(a)(6) of the Act).
Seat Lift	Covered under the conditions specified in §280.4 of this manual. Refer all to medical staff for this determination.
Self Contained Pacemaker Monitor	Covered when prescribed by a physician for a patient with a cardiac pacemaker. (See §§20.8.1 and 280.2 of this manual.)
Sitz Bath	Covered if the contractor's medical staff determines patient has an infection or injury of the perineal area and the item has been prescribed by the patient's physician as a part of his planned regimen of treatment in the patient's home.

Item	Coverage
Spare Tanks of Oxygen	Deny--convenience or precautionary supply.
Speech Teaching Machine	Deny--education equipment; not primarily medical in nature (§1861(n) of the Act).
Stairway Elevators	Deny--(See Elevators.) (§1861(n) of the Act).
Standing Table	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Steam Packs	These packs are Covered under the same condition as a heating pad. (See Heating Pads.)
Suction Machine	Covered if the contractor's medical staff determines that the machine specified in the claim is medically required and appropriate for home use without technical or professional supervision.
Support Hose	Deny (See Fabric Supports.) (§1861(n) of the Act).
Surgical Leggings	Deny--non-reusable supply; not rental-type item (§1861(n) of the Act).
Telephone Alert Systems	Deny--these are emergency communications systems and do not serve a diagnostic or therapeutic purpose.
Toilet Seats	Deny--not medical equipment (§1861(n) of the Act).
Traction Equipment	Covered if patient has orthopedic impairment requiring traction equipment which prevents ambulation during the period of use (Consider covering devices usable during ambulation; e.g., cervical traction collar, under the brace provision).
Trapeze Bars	Covered if patient is bed confined and the patient needs a trapeze bar to sit up because of respiratory condition, to change body position for other medical reasons, or to get in and out of bed.
Treadmill Exerciser	Deny--exercise equipment; not primarily medical in nature (§1861(n) of the Act).
Ultraviolet Cabinet	Covered for selected patients with generalized intractable psoriasis. Using appropriate consultation, the contractor should determine whether medical and other factors justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital.
Urinals autoclavable	Covered if patient is bed confined hospital type.
Vaporizers	Covered if patient has a respiratory illness.
Ventilators	Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive and negative pressure types. (See also §240.5 of this manual.)
Walkers	Covered if patient's condition impairs ambulation (See also §280.5 of this manual.)
Water and Pressure Pads and Mattresses	(See Alternating Pressure Pads, Mattresses and Lamb Wool Pads.)

Item	Coverage
Wheelchairs (power operated)	Covered if patient's condition is such and wheelchairs with other that a wheelchair is medically necessary special features and the patient is unable to operate the wheelchair manually. Any claim involving a power wheelchair or a wheelchair with other special features should be referred for medical consultation since payment for the special features is limited to those which are medically required because of the patient's condition. (See §280.9 for power operated and §280.3 for specially sized wheelchairs.) NOTE:A power-operated vehicle that may appropriately be used as a wheelchair can be Covered. (See §280.9 of this manual for coverage details.)
Whirlpool Bath Equipment	Covered if patient is homebound and has a (standard)condition for which the whirlpool bath can be expected to provide substantial therapeutic benefit justifying its cost. Where patient is not homebound but has such a condition, payment is restricted to the cost of providing the services elsewhere; e.g., an outpatient department of a participating hospital, if that alternative is less costly. In all cases, refer claim to medical staff for a determination.
Whirlpool Pumps	Deny--(See Portable Whirlpool Pumps.) (§1861(n) of the Act).
White Cane	Deny--(See §280.2 of this manual.)

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services."

The Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)."

280.2 - White Cane for Use by a Blind Person

(Rev. 1, 10-03-03)
CIM 60-3

Not Covered

A white cane for use by a blind person is more an identifying and self-help device than an item which makes a meaningful contribution in the treatment of an illness or injury.

280.3 - Specially Sized Wheelchairs

(Rev. 1, 10-03-03)
CIM 60-6

Payment may be made for a specially sized wheelchair even though it is more expensive than a standard wheelchair. For example, a narrow wheelchair may be required because of the narrow doorways of a patient's home or because of a patient's slender build. Such difference in the size of the wheelchair from the standard model is not considered a deluxe feature.

A physician's certification or prescription that a special size is needed is not required where the contractor can determine from the information in file or other sources that a specially sized wheelchair (rather than a standard one) is needed to accommodate the wheelchair to the place of use or the physical size of the patient.
To determine the reasonable charge in these cases, the contractor uses the criteria set out in the Medicare Claims Processing Manuals, Chapter 23, "Fee Schedule Administration and Coding Requirements," and Chapter 12, "Physician/ Practitioner Billing," as necessary.

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §110.

The Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §§30.5.3 and 20.2

The Medicare Benefit Policy Manual, Chapter 13, "Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services," §30.1.

280.4 - Seat Lift

(Rev. 1, 10-03-03)
CIM 60-8

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular disease when it has been determined the patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and that the severity of the condition is such that the alternative would be chair or bed confinement.

Coverage of seat lifts is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance. Excluded from coverage is the type of lift which operates by a spring release mechanism with a sudden, catapult-like motion and jolts the patient from a seated to a standing position. Limit the payment for units which incorporate a recliner feature along with the seat lift to the amount payable for a seat lift without this feature.

Cross Reference:

The Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §90.

280.5 - Safety Roller

(Rev. 1, 10-03-03)
CIM 60-15

Effective for Claims Adjudicated On or After June 3, 1985

"Safety roller" is the generic name applied to devices for patients who cannot use standard wheeled walkers. They may be appropriate, and therefore covered, for some patients who are obese, have severe neurological disorders, or restricted use of one hand which makes it impossible to use a wheeled walker that does not have the sophisticated braking system found on safety rollers.

In order to assure that payment is not made for a safety roller when a less expensive standard wheeled walker would satisfy the patient's medical needs, carriers should refer safety roller claims to their medical consultants. The medical consultant determines whether some or all of the features provided in a safety roller are necessary, and therefore covered and reimbursable. If it is determined that the patient could use a standard wheeled walker, the charge for the safety roller is reduced to the charge of a standard wheeled walker.

Some obese patients who could use a standard wheeled walker if their weight did not exceed the walker's strength and stability limits can have it reinforced and its wheel base expanded. Such modifications are routine mechanical adjustments and justify a moderate surcharge. In these cases the carrier reduces the charge for the safety roller to the charge for the standard wheeled walker plus the surcharge for modifications.

In the case of patients with medical documentation showing severe neurological disorders or restricted use of one hand which makes it impossible for them to use a wheeled walker that does not have a sophisticated braking system, a reasonable charge for the safety roller may be determined without relating it to the reasonable charge for a standard wheeled walker. (Such reasonable charge should be developed in accordance with the instructions in the Medicare Claims Processing Manual, Chapter 23, "Fee Schedule Administration and Coding Requirements.")

Cross Reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120, and §280.1 of this manual.

280.6 - Pneumatic Compression Devices

(Rev. 1, 10-03-03)
CIM 60-16

Pneumatic compression devices consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices. Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers.

Lymphedema

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition which may be due to such causes as Milroy's Disease or congenital anomalies. Secondary lymphedema which is much more common, results from the destruction of or damage to formerly functioning lymphatic channels, such as surgical removal of lymph nodes or post radiation fibrosis, among other causes.

Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

Chronic Venous Insufficiency With Venous Stasis Ulcers

Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers.

Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a six month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

General Coverage Criteria

Pneumatic compression devices are covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include:

1. The patient's diagnosis and prognosis;
2. Symptoms and objective findings, including measurements which establish the severity of the condition;
3. The reason the device is required, including the treatments which have been tried and failed; and
4. The clinical response to an initial treatment with the device.

The clinical response includes the change in pretreatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

The only time that a segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

Cross Reference: §280.1.

280.7 - Hospital Beds

(Rev. 1, 10-03-03)
CIM 60-18

A - General Requirements for Coverage of Hospital Beds

A physician's prescription, and such additional documentation as the contractors' medical staffs may consider necessary, including medical records and physicians' reports, must establish the medical necessity for a hospital bed due to one of the following reasons:

- The patient's condition requires positioning of the body; e.g., to alleviate pain, promote good body alignment, prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed; or
- The patient's condition requires special attachments that cannot be fixed and used on an ordinary bed.

B - Physician's Prescription

The physician's prescription which must accompany the initial claim, and supplementing documentation when required, must establish that a hospital bed is medically necessary. If the stated reason for the need for a hospital bed is the patient's condition requires positioning, the prescription or other documentation must describe the medical condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the condition, that necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is the patient's condition requires special attachments, the prescription must describe the patient's condition and specify the attachments that require a hospital bed.

C - Variable Height Feature

In well documented cases, the contractors' medical staffs may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered, for one of the following conditions:

- Severe arthritis and other injuries to lower extremities; e.g., fractured hip - The condition requires the variable height feature to assist the patient to ambulate by enabling the patient to place his or her feet on the floor while sitting on the edge of the bed;
- Severe cardiac conditions - For those cardiac patients who are able to leave bed, but who must avoid the strain of "jumping" up or down;
- Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputee and stroke patients. For those patients who are able to transfer from bed to a wheelchair, with or without help; or
- Other severely debilitating diseases and conditions, if the variable height feature is required to assist the patient to ambulate.

D - Electric Powered Hospital Bed Adjustments

Electric powered adjustments to lower and raise head and foot may be covered when the contractor's medical staff determines that the patient's condition requires frequent change in body position and/or there may be an immediate need for a change in body position (i.e., no delay can be tolerated) and the patient can operate the controls and cause the adjustments. Exceptions may be made to this last requirement in cases of spinal cord injury and brain damaged patients.

E - Side Rails

If the patient's condition requires bed side rails, they can be covered when an integral part of, or an accessory to, a hospital bed.

280.8 - Air-Fluidized Bed

(Rev. 1, 10-03-03)
CIM 60-19

Air fluidized beds are covered for services rendered on or after: July 30, 1990.
An air-fluidized bed uses warm air under pressure to set small ceramic beads in motion which simulate the movement of fluid. When the patient is placed in the bed, his body weight is evenly distributed over a large surface area which creates a sensation of "floating." Medicare payment for home use of the air-fluidized bed for treatment of pressure sores can be made if such use is reasonable and necessary for the individual patient.

A decision that use of an air-fluidized bed is reasonable and necessary requires that:

- The patient has a stage 3 (full thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore;
- The patient is bedridden or chair bound as a result of severely limited mobility;
- In the absence of an air-fluidized bed, the patient would require institutionalization;
- The air-fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. This course of treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment has been rendered.
- Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days, will not preclude coverage of air-fluidized bed. Should additional debridement again become necessary, while a patient is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to become noncovered. In all instances documentation verifying the continued need for the bed must be available.
- A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage;
- A physician directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis; and
- All other alternative equipment has been considered and ruled out.

Conservative treatment must include:

- Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hours);

- Use of a specialized support surface (Group II) designed to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation;
- Necessary treatment to resolve any wound infection;
- Optimization of nutrition status to promote wound healing;
- Debridement by any means (including wet to dry dressings-which does not require an occlusive covering) to remove devitalized tissue from the wound bed;
- Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

Home use of the air-fluidized bed is not covered under any of the following circumstances:

- The patient has coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);
- The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material;
- The caregiver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed;
- Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs 1600 pounds or more);
- Electrical system is insufficient for the anticipated increase in energy consumption; or
- Other known contraindications exist.

Coverage of an air-fluidized bed is limited to the equipment itself. Payment for this covered item may only be made if the written order from the attending physician is furnished to the supplier prior to the delivery of the equipment. Payment is not included for the caregiver or for architectural adjustments such as electrical or structural improvement.

Cross reference:

The Medicare Claims Processing Manual, Chapter 23, "Fee Schedule Administration and Coding Requirements," §§60.

280.9 - Power Operated Vehicles That May Be Used as Wheelchairs

(Rev. 1, 10-03-03)
CIM 60-5

Power-operated vehicles that may be appropriately used as wheelchairs are covered under the durable medical equipment provision.

These vehicles have been appropriately used in the home setting for vocational rehabilitation and to improve the ability of chronically disabled persons to cope with normal

domestic, vocational and social activities. They may be covered if a wheelchair is medically necessary and the patient is unable to operate a wheelchair manually. A specialist in physical medicine, orthopedic surgery, neurology, or rheumatology must provide an evaluation of the patient's medical and physical condition and a prescription for the vehicle to assure that the patient requires the vehicle and is capable of using it safely. When a durable medical equipment regional carrier (DMERC) determines that such a specialist is not reasonably accessible, e.g., more than one day's round trip from the beneficiary's home, or the patient's condition precludes such travel, a prescription from the beneficiary's physician is acceptable.

The DMERC's medical staff reviews all claims for a power-operated vehicle, including the specialists' or other physicians' prescriptions and evaluations of the patient's medical and physical conditions, to insure that all coverage requirements are met. (See §280.1 and the Medicare Claims Processing Manual, Chapter 20,"Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §§110, 120, 130, 140, 150, 160, and 170.)

280.10 - Prosthetic Shoe

(Rev. 1, 10-03-03)
CIM 70-3

A prosthetic shoe (a device used when all or a substantial portion of the front part of the foot is missing) can be covered as a terminal device; i.e., a structural supplement replacing a totally or substantially absent hand or foot. The coverage of artificial arms and legs includes payment for terminal devices such as hands or hooks even though the patient may not require an artificial limb. The function of the prosthetic shoe is quite distinct from that of excluded orthopedic shoe and supportive foot devices which are used by individuals whose feet, although impaired, are essentially intact. (Section 1862(a)(8) of the Act excludes payment for orthopedic shoes or other supportive devices for the feet.) See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Services," §130.

280.11 - Corset Used as Hernia Support

(Rev. 1, 10-03-03)
CIM 70-1

A hernia support (whether in the form of a corset or truss) which meets the definition of a brace is covered under Part B under §1861(s)(9) of the Act. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Services," §130.

280.12 - Sykes Hernia Control

(Rev. 1, 10-03-03)
CIM 70-2

Based on professional advice, it has been determined that the sykes hernia control (a spring-type, U-shaped, strapless truss) is not functionally more beneficial than a

conventional truss. Make program reimbursement for this device only when an ordinary truss would be covered. (Like all trusses, it is only of benefit when dealing with a reducible hernia). Thus, when a charge for this item is substantially in excess of that which would be reasonable for a conventional truss used for the same condition, base reimbursement on the reasonable charges for the conventional truss. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Services," §130.

280.13 - Transcutaneous Electrical Nerve Stimulators (TENS)

(Rev. 1, 10-03-03)
CIM 60-20

The TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit. (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS and §10.2 for an explanation of coverage of TENS for acute post-operative pain.)

280.14 – Infusion Pumps

(Rev. 1, 10-03-03)
CIM 60-14

The following indications for treatment using infusion pumps are covered under Medicare:

A - External Infusion Pumps

1 - Iron Poisoning - Effective for Services Performed On or After 9/26/84.

When used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

2 - Thromboembolic Disease - Effective for Services Performed On or After 9/26/84
When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

3 - Chemotherapy for Liver Cancer - Effective for Services Performed On or After 1/29/85.

The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor.

4 - Morphine for Intractable Cancer Pain - Effective for Services Performed On or After 4/22/85.

Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice).

5 - Continuous subcutaneous insulin infusion pumps (CSII) - Effective for Services Performed On or after 4/1/2000.

An external infusion pump and related drugs/supplies are covered as medically necessary in the home setting in the following situation:

Treatment of diabetes

In order to be covered, patients must meet criterion a or b:

Criterion a

The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:

1. Glycosylated hemoglobin level (HbAlc) > 7.0 percent
2. History of recurring hypoglycemia
3. Wide fluctuations in blood glucose before mealtime
4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
5. History of severe glycemic excursions

Criterion b

1. The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

Diabetes needs to be documented by a fasting C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method. Effective for Services Performed on or after January 1, 2002.

Continued coverage of the insulin pump would require that the patient has been seen and evaluated by the treating physician at least every three months.

The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.

6 - Other Uses

Other uses of external infusion pumps are covered if the contractor's medical staff verifies the appropriateness of the therapy and of the prescribed pump for the individual patient.

NOTE: Payment may also be made for drugs necessary for the effective use of an external infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

B - Implantable Infusion Pumps

1 - Chemotherapy for Liver Cancer

Effective for Services Performed On or After 9/26/84.

The implantable infusion pump is covered for intra-arterial infusion of 5-FUdR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable or (2) where the patient refuses surgical excision of the tumor.

2 - Anti-Spasmodic Drugs for Severe Spasticity

An implantable infusion pump is covered when used to administer anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

As indicated by at least a 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects, and

Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

3 - Opioid Drugs for Treatment of Chronic Intractable Pain

An implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least three

months and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

The patient's history must indicate that he/she would not respond adequately to noninvasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and

A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.

4 - Coverage of Other Uses of Implanted Infusion Pumps

Determinations may be made on coverage of other uses of implanted infusion pumps if the contractor's medical staff verifies that:

- The drug is reasonable and necessary for the treatment of the individual patient;
- It is medically necessary that the drug be administered by an implanted infusion pump; and
- The FDA approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.

5 - Implantation of Infusion Pump Is Contraindicated

The implantation of an infusion pump is contraindicated in the following patients:

- Patients with a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);
- Patients who have an infection;
- Patients whose body size is insufficient to support the weight and bulk of the device; and
- Patients with other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

NOTE: Payment may also be made for drugs necessary for the effective use of an implantable infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

Infusion Pumps Not Covered

The following indications for treatment using infusion pumps are not covered under Medicare:

External Infusion Pumps

Vancomycin

Effective for Services Beginning On or After September 1, 1996.

Medicare coverage of vancomycin as a durable medical equipment infusion pump benefit is not covered. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.
Implantable Infusion Pump

A - Thromboembolic Disease

Effective for Services Performed On or After 9/26/84.

According to the Public Health Service, there is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump. Therefore, the use of an implantable infusion pump for infusion of heparin in the treatment of recurrent thromboembolic disease is not covered.

B - Diabetes

An implanted infusion pump for the infusion of insulin to treat diabetes is not covered. The data does not demonstrate that the pump provides effective administration of insulin.

290 - Nursing Services

(Rev. 1, 10-03-03)

290.1 - Home Health Visits to a Blind Diabetic

(Rev. 1, 10-03-03)
CIM 90-1

Many individuals who are blind and require daily insulin for the control of a diabetic condition are able to administer their injections without assistance (other than possibly that which may be furnished by family members or friends). There are organizations which encourage and train blind diabetics, both to fill their own syringes and to inject themselves. There are also a number of devices available for blind individuals to fill their syringes accurately. However, the individuals who may need assistance with prefilling their syringes may also require periodic observation and evaluation, even though their diabetes is fairly stabilized. In such cases, probably few in number, home health services may be required for this purpose.

To qualify for home health benefits, a blind diabetic must be confined to his home, under the care of a physician, and in need of either skilled nursing services on an intermittent basis or physical therapy or speech therapy. Effective July 1, 1981, a person may qualify for home health benefits based on his or her need for skilled nursing services on an intermittent basis, physical therapy, speech therapy, or occupational therapy. Effective December 1, 1981, occupational therapy is eliminated as a basis for entitlement to home health services. However, if a person has otherwise qualified for home health services because of the need for skilled nursing care, physical therapy or speech therapy, the patient's eligibility for home health services may be extended solely on the basis of the continuing need for occupational therapy. (See the Medicare Benefit Policy Manual, Chapter 7, "Home Health Services," §20.) There must be a plan of treatment, established and periodically reviewed by a physician which indicates that there is a recurring need for home health services to supplement the physician's contacts with the patient; e.g., skilled nursing visits for observing and determining the need for changes in the level and type of care which has been prescribed. (See the Medicare Benefit Policy Manual, Chapter 7, "Home Health Services," §§30.) Once an initial regimen has been established, the frequency of need for further home health services can vary greatly from patient to patient, depending on their condition and the likelihood of its changing. Some may need visits only every 90 days, for example, while others may require them much more frequently. If a nurse makes a visit to provide skilled services, and also prefills syringes, the purpose of the visit which was to provide skilled services, does not change. However, if the sole purpose of the nurse's visit is to prefill insulin syringes for a blind diabetic, it is not a skilled nursing visit although it may be reimbursed as such as indicated below.

Filling a syringe can be safely and effectively performed by the average nonmedical person without the direct supervision of a licensed nurse. Consequently, it would not constitute a skilled nursing service even if it is performed by a nurse. (See the Medicare Benefit Policy Manual, Chapter 7, "Home Health Services," §30.2.2.) The personal care duties normally performed by home health aides include assisting the patient with medications ordered by a physician which are ordinarily self-administered. (See the Medicare Benefit Policy Manual, Chapter 7, "Home Health Services," §50.2.)

Performance of such a service by an aide is consistent with the Medicare conditions of participation for home health agencies. Therefore, home health aide services would be appropriate for those blind diabetics who are qualified for home health benefits and who cannot fill their syringes. An adequately trained home health aide could make intermittent visits, usually on a weekly basis, to the home for the purpose of filling that supply of insulin ordered by the physician.

If State law, however, precludes a home health aide from prefilling insulin syringes, payment may be made for this service as part of the cost of skilled nursing services when performed by a nurse for a blind diabetic who is otherwise unable to prefill his or her syringes. There are no adverse consequences with respect to reimbursement to the home health agency for providing the service in this manner.

If State law does not preclude a home health aide from prefilling insulin syringes, but the home health agency chooses to send a nurse to perform only this task, the visit is reimbursed as if made by a home health aide.

NOTE: As indicated, to qualify for home health benefits, a patient must require skilled nursing services on an intermittent basis or physical therapy or speech therapy. If a beneficiary does not qualify for home health benefits but only needs someone to prefill syringes with the correct dosage of insulin, then no program payment can be made.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 7, "Home Health Services," §§20, §§30, §30.2.2 and, §§50.

290.2 - Home Health Nurses' Visits to Patients Requiring Heparin Injections

(Rev. 1, 10-03-03)
CIM 90-2

Professional medical advice indicates that subcutaneous injections of low dose heparin can be, under certain circumstances, medically accepted therapy for the treatment of recurrent deep venous thrombosis, recurrent pulmonary emboli, and other conditions requiring long term anticoagulation. The usual drug of choice for these conditions is warfarin. Heparin may be substituted for warfarin in circumstances such as demonstrated warfarin sensitivity. Heparin is now the drug of choice for anticoagulation during pregnancy.

Medicare payment may be made for serial visits by the home health nurse to teach the patient or the caring person to give subcutaneous injections of low dose heparin if it is prescribed by a physician for a homebound patient who:

- Is pregnant and requires anticoagulant therapy, or

- Requires treatment for deep venous thrombosis or pulmonary emboli or for another condition requiring anticoagulation and documentation justifies that the patient cannot tolerate warfarin.

If the patient or caring person is unable to administer the injection, nursing visits to give the injections on a daily basis, seven days a week, for a period of up to six months (in the case of pregnancy, visits may be made for a period beyond six months if reasonable and necessary) would be reimbursed by Medicare. Coverage for these services after six months of treatment would be provided only if the prescribing physician can justify and document the need for such an extended course of treatment. Documentation of need for heparin injections beyond six months would not be required for pregnant patients who meet the homebound criteria.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 7, "Home Health Services," §§30.4,

300 - Diagnostic Tests Not Otherwise Classified (Rev.)

300.1 - Obsolete or Unreliable Diagnostic Tests

(Rev. 1, 10-03-03)
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 seromucoid 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:

- CPT code 93201, Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician),
- CPT code 93202, Phonocardiogram; tracing only, without interpretation and report (e.g., when equipment is supplied by the hospital, clinic),
- CPT code 93204, Phonocardiogram; interpretation and report,
- CPT code 93205, Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report,
- CPT code 93208, Phonocardiogram; without interpretation and report,
- CPT code 93209, Phonocardiogram; interpretation and report only,
- CPT code 93210, Intracardiac,
- CPT code 93220, Vectorcardiogram (VCG), with or without ECG; with interpretation and report,
- CPT code 93221, Vectorcardiogram; tracing only, without interpretation and report, and
- CPT code 93222, Vectorcardiogram; interpretation and report only.

CPT codes 93201, 93202, 93204, 93205, 93208, 93209, 93210, 93220, 93221, and 93222 have been deleted, to report, use 93799 cardiovascular procedure.

310 - Clinical Trials

(Rev. 1, 10-03-03)

310.1 - Routine Costs in Clinical Trails

(Rev. 1, 10-03-03)
CIM 30-1

Effective for items and services furnished on or after September 19, 2000, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

The investigational item or service, itself;

Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

Items or services that are typically provided absent a clinical trial (e.g., conventional care);

Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service - in particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201 - 405.215, 411.15, and 411.406. For information about local medical review policies (LMRPs), refer to http://www.lmrp.net/, a searchable database of Medicare contractors' local policies.

For noncovered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the noncovered item or service and unrelated reasonable and necessary care. (Refer to MCM §§2300.1 and MIM 3101.) However, if the item or service is not covered by virtue of a national noncoverage policy in the Coverage Issues Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the noncovered item or service, itself,

will not. Requirements for Medicare Coverage of Routine Costs.--Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

The trial does not unjustifiably duplicate existing studies;

The trial design is appropriate to answer the research question being asked in the trial;

The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

The trial is in compliance with Federal regulations relating to the protection of human subjects; and

All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Qualification Process for Clinical Trials:

Using the authority found in §1142 of the Act (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH),

Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to HCFA.

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA;

Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;

Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and

Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified or have certified that they meet the qualifying criteria unless HCFA's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should HCFA find that a trial's principal investigator misrepresented that the trial met the

necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable.Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

Medicare regulations require Medicare+Choice (M+C) organizations to follow HCFA's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.