Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.25)

Coverage Determinations

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(Rev. 1, 10-03-03)
No coverage determinations

100 - Gastrointestinal System

(Rev. 1, 10-03-03)

100.1 - Gastric Bypass Surgery for Obesity

(Rev. 1, 10-03-03)
CIM 35-40

Gastric bypass surgery which is a variation of the gastrojejunostomy, is performed for patients with extreme obesity. Gastric bypass surgery for extreme obesity is covered under the program if (1) it is medically appropriate for the individual to have such surgery; and (2) the surgery is to correct an illness which caused the obesity or was aggravated by the obesity.

Cross-references: §§40.5 and 100.8.

100.2 - Endoscopy

(Rev. 1, 10-03-03)
CIM 35-59

Endoscopy is a technique in which a long flexible tube-like instrument is inserted into the body orally or rectally, permitting visual inspection of the gastrointestinal tract. Although primarily a diagnostic tool, endoscopy includes certain therapeutic procedures such as removal of polyps, and endoscopic papillotomy, by which stones are removed from the bile duct.

Endoscopic procedures are covered when reasonable and necessary for the individual patient.

100.3 - 24-Hour Ambulatory Esophegeal pH Monitoring

(Rev. 1, 10-03-03)
CIM 35-83

Twenty-four hour ambulatory esophageal pH monitoring is a diagnostic procedure involving the placement of an indwelling electrode into the lower esophagus of a patient for the purpose of determining the presence of gastric reflux and measuring abnormal esophageal acid exposure.

Twenty-four hour ambulatory pH monitoring is covered by Medicare for patients who are suspected of having gastric reflux, but only if the patient presents diagnostic problems associated with atypical symptoms or the patient's symptoms are suggestive of reflux, but conventional tests have not confirmed the presence of reflux.

100.4 - Esophageal Manometry

(Rev. 1, 10-03-03)
CIM 50-25

Esophageal manometry is covered under Medicare where it is determined to be reasonable and necessary for the individual patient. The major use of esophageal manometry is to measure pressure within the esophagus to assist in the diagnosis of esophageal pathology including aperistalsis, spasm, achalasia, esophagitis, esophageal ulcer, esophageal congenital webs, diverticuli, scleroderma, hiatus hernia, congenital cysts, benign and malignant tumors, hypermobility, hypomobility, and extrinsic lesions. Esophageal manometry is mostly used in difficult diagnostic cases and as an adjunct to x-rays and direct visualization of the esophagus (endoscopy) through the fiberscope.

100.5 - Diagnostic Breath Analyses

(Rev. 1, 10-03-03)
CIM 50-51

Diagnostic breath analyses are tests performed to measure either the hydrogen or carbon dioxide content of the breath after the ingestion of certain compounds. The analyses are performed to diagnose certain gastrointestinal disease states.

The Following Breath Test Is Covered:

Lactose breath hydrogen to detect lactose malabsorption.

The Following Breath Tests Are Excluded From Coverage:

Lactulose breath hydrogen for diagnosing small bowel bacterial overgrowth and measuring small bowel transit time.

CO2 for diagnosing bile acid malabsorption.
CO2 for diagnosing fat malabsorption.

100.6 - Gastric Freezing

(Rev. 1, 10-03-03)
CIM 35-65

Gastric freezing for chronic peptic ulcer disease is a non-surgical treatment which was popular about 20 years ago but now is seldom done. It has been abandoned due to a high complication rate, only temporary improvement experienced by patients, and lack of effectiveness when tested by double-blind, controlled clinical trials. Since the procedure is now considered obsolete, it is not covered.

100.7 - Colonic Irrigation

CIM 35-1
Not Covered

Colonic irrigation is a procedure to wash out or lavage material on the walls of the bowel to an unlimited distance without inducing defecation. This procedure is distinguished from all types of enemas which are primarily used to induce defecation.

There are no conditions for which colonic irrigation is medically indicated and no evidence of therapeutic value. Accordingly, colonic irrigation cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

100.8 - Intestinal Bypass Surgery

(Rev. 1, 10-03-03)
CIM 35-33

Not Covered

The safety of intestinal bypass surgery for treatment of obesity has not been demonstrated. Severe adverse reactions such as steatorrhea, electrolyte depletion, liver failure, arthralgia, hypoplasia of bone marrow, and avitaminosis have sometimes occurred as a result of this procedure. It does not meet the reasonable and necessary provisions of §1862(a)(1) of the Act and is not a covered Medicare procedure.
Cross-references: §§40.5, 100.1.

100.9 - Implantation of Anti-Gastroesophageal Reflux Device

(Rev. 1, 10-03-03)
CIM 35-69

The implantation of an anti-gastroesophageal reflux device is a surgical procedure for the treatment of gastroesophageal reflux, a condition in which the caustic contents of the stomach flow back into the esophagus. The procedure involves the implantation of this special device around the esophagus under the diaphragm and above the stomach which is secured in place by a circumferential tie strap.

The implantation of this device may be considered reasonable and necessary in specific clinical situations where a conventional valvuloplasty procedure is contraindicated. The implantation of an anti-gastroesophageal reflux device is covered only for patients with documented severe or life threatening gastroesophageal reflux disease whose conditions have been resistant to medical treatment and who also:

- Have esophageal involvement with progressive systemic sclerosis; or
- Have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction; or
- Are poor surgical risks for a valvuloplasty procedure; or

- Have failed previous attempts at surgical treatment with valvuloplasty procedures.

100.10 - Injection Sclerotherapy for Esophageal Variceal Bleeding

(Rev. 1, 10-03-03)
CIM 35-73

Injection sclerotherapy is a technique involving insertion of a flexible fiberoptic endoscope into the esophagus, and the injection of a sclerosing agent or solution into the varicosities to control bleeding. This procedure is covered under Medicare

100.11 - Gastric Balloon for Treatment of Obesity

(Rev. 1, 10-03-03)
CIM 35-86

Not Covered

The gastric balloon is a medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety.

The use of the gastric balloon is not covered under Medicare, since the long term safety and efficacy of the device in the treatment of obesity has not been established.

100.12 - Gastrophotography

(Rev. 1, 10-03-03)
CIM 50-9

Gastrophotography is an accepted procedure for diagnosis and treatment of gastro-intestinal disorders. The photographic record provided by this procedure is often necessary for consultation and/or follow-up purposes and when required for such purposes, is more valuable than a conventional gastroscopic examination. Such a record facilitates the documentation and evaluation (healing or worsening) of lesions such as the gastric ulcer, facilitates consultation between physicians concerning difficult-to-interpret lesions, provides preoperative characterization for the surgeon, and permits better diagnosis of postoperative gastric bleeding to help determine whether there is a need for another operation. Therefore, program reimbursement may be made for this procedure.

100.13 - Laproscopic Cholecystectomy

(Rev. 1, 10-03-03)
CIM 35-91

Laparoscopic cholecystectomy is a covered surgical procedure in which a diseased gall bladder is removed through the use of instruments introduced via cannulae, with vision of the operative field maintained by use of a high-resolution television camera-monitor

system (video laparoscope). For inpatient claims, use ICD-9-CM code 51.23, Laparoscopic cholecystectomy. For all other claims, use CPT codes 47562 for laparoscopy, surgical; cholecystectomy (any method), and 47563 for laparoscopy, surgical: cholecystectomy with cholangiography.

110 - Hematology/Immunology/Oncology

(Rev. 1, 10-03-03)

110.1 - Hyperthermia for Treatment of Cancer

(Rev. 1, 10-03-03)
CIM 35-49

Local hyperthermia for treatment of cancer consists of the use of heat to make tumors more susceptible to cancer therapy measures.

Local hyperthermia is covered under Medicare when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy.

110.2 - Certain Drugs Distributed by the National Cancer Institute

(Rev. 1, 10-03-03)
CIM 45-16

Under its Cancer Therapy Evaluation, the Division of Cancer Treatment of the National Cancer Institute (NCI), in cooperation with the Food and Drug Administration, approves and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, are not limited to use in clinical trials for the purpose of testing their efficacy. Drugs are classified as Group C drugs only if there is sufficient evidence demonstrating their efficacy within a tumor type and that they can be safely administered.

A physician is eligible to receive Group C drugs from the Division of Cancer Treatment only if the following requirements are met:

- A physician must be registered with the NCI as an investigator by having completed an FD-Form 1573;
- A written request for the drug, indicating the disease to be treated, must be submitted to the NCI;
- The use of the drug must be limited to indications outlined in the NCIs guidelines; and
- All adverse reactions must be reported to the Investigational Drug Branch of the Division of Cancer Treatment.

In view of these NCI controls on distribution and use of Group C drugs, intermediaries may assume, in the absence of evidence to the contrary, that a Group C drug and the related hospital stay are covered if all other applicable coverage requirements are satisfied.

If there is reason to question coverage in a particular case, the matter should be resolved with the assistance of the Quality Improvement Organization (QIO), or if there is none, the assistance of the contractor's medical consultants.
Information regarding those drugs which are classified as Group C drugs may be obtained from:

Office of the Chief, Investigational Drug Branch
Division of Cancer Treatment, CTEP, Landow Building
Room 4C09, National Cancer Institute
Bethesda, Maryland 20205

110.3 - Anti-Inhibitor Coagulant Complex (AICC)

(Rev. 1, 10-03-03)
CIM 45-24

Anti-inhibitor coagulant complex, AICC, is a drug used to treat hemophilia in patients with factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and has Medicare coverage when furnished to patients with hemophilia A and inhibitor antibodies to factor VIII who have major bleeding episodes and who fail to respond to other, less expensive therapies.

110.4 - Extracorporeal Photopheresis

(Rev. 1, 10-03-03)
CIM 35-88

Extracorporeal photopheresis is a treatment for cutaneous T-cell lymphoma (CTCL), a condition that is generally resistant to chemotherapy and radiotherapy. The treatment begins with the oral administration of the drug methoxsalen. The patient's blood is then passed through a device that permits exposure of the blood, while it is outside the body (extracorporeal), to ultraviolet A light. The blood is then returned to the patient. Extracorporeal photopheresis is covered by Medicare only when used in the palliative treatment of the skin manifestations of CTCL that has not responded to other therapy.

110.5 - Granulocyte Transfusions

(Rev. 1, 10-03-03)
CIM 45-18

Granulocyte transfusions to patients suffering from severe infection and granulocytopenia are a covered service under Medicare. Granulocytopenia is usually identified as fewer

than 500 granulocytes/mm^3 whole blood. Accepted indications for granulocyte transfusions include:

- Granulocytopenia with evidence of gram negative sepsis; and
- Granulocytopenia in febrile patients with local progressive infections unresponsive to appropriate antibiotic therapy, thought to be due to gram negative organisms.

110.6 - Scalp Hypothermia During Chemotherapy to Prevent Hair Loss

(Rev. 1, 10-03-03)
CIM 45-21

Keeping the scalp cool during chemotherapy has been noted to reduce the risk of hair loss. The cooling may be done by packing the scalp with ice-filled bags or bandages, or by specially designed devices filled with cold-producing chemicals activated during chemotherapy.

While ice-filled bags or bandages or other devices used for scalp hypothermia during chemotherapy may be covered as supplies of the kind commonly furnished without a separate charge, no separate charge for them would be recognized.

110.7 - Blood Transfusions

(Rev. 1, 10-03-03)
CIM 45-27

Blood transfusions are used to restore blood volume after hemorrhage, to improve the oxygen carrying capacity of blood in severe anemia, and to combat shock in acute hemolytic anemia.

A - Definitions

1 - Homologous Blood Transfusion

Homologous blood transfusion is the infusion of blood or blood components that have been collected from the general public.

2 - Autologous Blood Transfusion

An autologous blood transfusion is the precollection and subsequent infusion of a patient's own blood.

3 - Donor Directed Blood Transfusion

A donor directed blood transfusion is the infusion of blood or blood components that have been precollected from a specific individual(s) other than the patient and subsequently infused into the specific patient for whom the blood is designated. For example, patient B's brother predeposits his blood for use by patient B during upcoming surgery.

4 - Perioperative Blood Salvage

Perioperative blood salvage is the collection and reinfusion of blood lost during and immediately after surgery.

B - Policy Governing Transfusions

For Medicare coverage purposes, it is important to distinguish between a transfusion itself and preoperative blood services; e.g., collection, processing, storage. Medically necessary transfusion of blood, regardless of the type, may generally be a covered service under both Part A and Part B of Medicare. Coverage does not make a distinction between the transfusion of homologous, autologous, or donor-directed blood. With respect to the coverage of the services associated with the preoperative collection, processing, and storage of autologous and donor-directed blood, the following policies apply.

1 - Hospital Part A and B Coverage and Payment

Under §1862(a)(14) of the Act, nonphysician services furnished to hospital patients are covered and paid for as hospital services. As provided in §1886 of the Act, under the prospective payment system (PPS), the diagnosis related group (DRG) payment to the hospital includes all covered blood and blood processing expenses, whether or not the blood is eventually used.

In a situation where the hospital operates its own blood collection activities, rather than using an independent blood supplier, the costs incurred to collect autologous or donor-directed blood are recorded in the whole blood and packed red blood cells cost center. Because the blood has been replaced, Medicare does not recognize a charge for the blood itself. Under PPS, the DRG payment is intended to pay for all covered blood and blood services, whether or not the blood is eventually used.

Under its provider agreement, a hospital is required to furnish or arrange for all covered services furnished to hospital patients. Medicare payment is made to the hospital, under PPS or cost reimbursement, for covered inpatient and outpatient services, and it is intended to reflect payment for all costs of furnishing those services.

2 - Nonhospital Part B Coverage

Under Part B, to be eligible for separate coverage, a service must fit the definition of one of the services authorized by §1832 of the Act. These services are defined in 42 CFR 410.10 and do not include a separate category for a supplier's services associated with blood donation services, either autologous or donor-directed. That is, the collection, processing, and storage of blood for later transfusion into the beneficiary is not recognized as a separate service under Part B. Therefore, there is no avenue through which a blood supplier can receive direct payment under Part B for blood donation services.

C - Perioperative Blood Salvage

When the perioperative blood salvage process is used in surgery on a hospital patient, payment made to the hospital (under PPS or through cost reimbursement) for the procedure in which that process is used is intended to encompass payment for all costs relating to that process.

110.8 - Blood Platelet Transfusions

(Rev. 1, 10-03-03)
CIM 35-30

Blood platelet transplants are safe and effective for the correction of thrombocytopenia and other blood defects. It is covered under Medicare when treatment is reasonable and necessary for the individual patient.

110.8.1 - Stem Cell Transplantation

(Rev. 13, 05-28-04)
CIM 35-30.1

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. The transplant can be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

A - Allogeneic Stem Cell Transplantation

Allogeneic stem cell transplantation is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion.

1 - Covered Conditions - The following uses of allogeneic bone marrow transplantation are covered under Medicare:

- For the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary; and

- For the treatment of severe combined immunodeficiency disease (SCID), and for the treatment of Wiskott - Aldrich syndrome.

2 - Noncovered Conditions - Allogeneic stem cell transplantation is not covered as treatment for multiple myeloma.

B - Autologous Stem Cell Transplantation

Autologous stem cell transplantation is a technique for restoring stem cells using the patient's own previously stored cells.

1 - Covered Conditions - Autologous stem cell transplantation is considered reasonable and necessary under §1862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:

- Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;
- Resistant non-Hodgkin's or those presenting with poor prognostic features following an initial response;
- Recurrent or refractory neuroblastoma; or
- Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.

Effective October 1, 2000, single AuSCT is only covered for Durie-Salmon Stage II or III patients that fit the following requirement:

a. Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50 percent decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and
b. Adequate cardiac, renal, pulmonary, and hepatic function.

NOTE: Tandem transplantation for multiple myeloma remains noncovered.

2 - Noncovered Conditions - Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following conditions:

- Acute leukemia not in remission;
- Chronic granulocytic leukemia;
- Solid tumors (other than neuroblastoma);
- Up to October 1, 2000, multiple myeloma;
- Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma;
- Effective October 1, 2000, non-primary (AL) amyloidosis; and
- Effective October 1, 2000, primary (AL) amyloidosis for Medicare beneficiaries age 64 or older.

In these cases, autologous stem cell transplantation is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.

110.9 - Antigens Prepared for Sublingual Administration

(Rev. 1, 10-03-03)
CIM 45-28

For antigens provided to patients on or after November 17, 1996, Medicare does not cover such antigens if they are to be administered sublingually, i.e., by placing drops under the patient's tongue. This kind of allergy therapy has not been proven to be safe and effective. Antigens are covered only if they are administered by injection.

110.10 - Intravenous Iron Therapy

(Rev. 1, 10-03-03)
CIM 45-29

Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing hemodialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) that transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hematocrit levels. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. Body iron stores can be supplemented with either oral or intravenous (IV) iron products. The available evidence suggests that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia.

Effective December 1, 2000, Medicare covers sodium ferric gluconate complex in sucrose injection as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy.

Effective October 1, 2001, Medicare also covers iron sucrose injection as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy.

110.11 - Food Allergy Testing and Treatment

(Rev. 1, 10-03-03)
CIM 50-53

Not Covered

Effective October 31, 1988, sublingual intracutaneous and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are excluded from Medicare coverage because available evidence does not show that these tests and

therapies are effective. This exclusion was published as a Final Notice in the "Federal Register" on September 29, 1988.

110.12 - Challenge Ingestion Food Testing

(Rev. 1, 10-03-03)
CIM 50-22

Challenge ingestion food testing is a safe and effective technique in the diagnosis of food allergies. This procedure is covered when it is used on an outpatient basis if it is reasonable and necessary for the individual patient.
Challenge ingestion food testing has not been proven to be effective in the diagnosis of rheumatoid arthritis, depression, or respiratory disorders. Accordingly, its use in the diagnosis of these conditions is not reasonable and necessary within the meaning of §1862(a)(1) of the Act, and no program payment is made for this procedure when it is so used.

110.13 - Cytotoxic Food Tests

(Rev. 1, 10-03-03)
CIM 50-2

Not Covered

Prior to August 5, 1985, Medicare covered cytotoxic food tests as an adjunct to in vivo clinical allergy tests in complex food allergy problems. Effective August 5, 1985, cytotoxic leukocyte tests for food allergies are excluded from Medicare coverage because available evidence does not show that these tests are safe and effective. This exclusion was published as a CMS Ruling in the "Federal Register" on July 5, 1985.

110.14 - Apheresis (Therapeutic Pheresis)

(Rev. 1, 10-03-03)
CIM 35-60

A - General

Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, plataelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken.

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

B - Indications

Apheresis is covered for the following indications:

- Plasma exchange for acquired myasthenia gravis;
- Leukaphersis in the treatment of leukemia;
- Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- Plasmapheresis or plasma exchange as a last resort treatment of thromobotic thrombocytopenic purpura (TTP);
- Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;
- Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease;
- Plasma exchange in the treatment of Goodpasture's Syndrome;
- Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
- Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
- Treatment of Guillain-Barre Syndrome; and
- Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

C - Settings

Apheresis is covered only when performed in a hospital setting (either inpatient or outpatient); or in a nonhospital setting, e.g., a physician directed clinic when the following conditions are met:

- A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
- Each patient is under the care of a physician; and
- All nonphysician services are furnished under the direct, personal supervision of a physician.

110.15 - Ultrafiltration, Hemoperfusion and Hemofiltration

(Rev. 1, 10-03-03)
CIM 35-38

A - Ultrafiltration

This is a process for removing excess fluid from the blood through the dialysis membrane by means of pressure. It is not a substitute for dialysis. Ultrafiltration is utilized in cases where excess fluid cannot be removed easily during the regular course of hemodialysis. When it is performed, it is commonly done during the first hour or two of each hemodialysis on patients who, e.g., have refractory edema. Ultrafiltration is a covered procedure under the Medicare program (effective for services performed on and after September 1, 1979)

Predialysis Ultrafiltration

While this procedure requires additional staff care, the facility dialysis rate is intended to cover the full range of complicated and uncomplicated nonacute dialysis treatments. Therefore, no additional facility charge is recognized for predialysis ultrafiltration. The physician's role in ultrafiltration varies with the stability of the patient's condition. In unstable patients, the physician may need to be present at the initiation of dialysis, and available either in-house or in close proximity to monitor the patient carefully. In patients who are relatively stable, but who seem to accumulate excessive weight gain, the procedure requires only a modest increase in physician involvement over routine outpatient hemodialysis.

Occasionally, medical complications may occur which require that ultrafiltration be performed separate from the dialysis treatment, and in these cases an additional charge can be recognized. However, the claim must be documented as to why the ultrafiltration could not have been performed at the same time as the dialysis.

B - Hemoperfusion

This is a process which removes substances from the blood using a charcoal or resin artificial kidney. When used in the treatment of life threatening drug overdose, hemoperfusion is a covered service for patients with or without renal failure. Hemoperfusion generally requires a physician to be present to initiate treatment and to be present in the hospital or an adjacent medical office during the entire procedure, as changes may be sudden. Special staff training and equipment are required. Develop charges for hemoperfusion in the same manner as for any new or unusual service. One or two treatments are usually all that is necessary to remove the toxic compound; document additional treatments. Hemoperfusion may be performed concurrently with dialysis, and in those cases payment for the hemoperfusion reflects only the additional care rendered over and above the care given with dialysis.

The effects of using hemoperfusion to improve the results of chronic hemodialysis are not known. Therefore, hemoperfusion is not a covered service when used to improve the results of hemodialysis. In addition, it has not been demonstrated that the use of hemoperfusion in conjunction with deferoxamine (DFO), in treating symptomatic patients with iron overload, is efficacious. There is also a paucity of data regarding its efficacy in treating asymptomatic patients with iron overload. Therefore, hemoperfusion used in conjunction with DFO in treating patients with iron overload is not a covered service; i.e., it is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

However, the use of hemoperfusion in conjunction with DFO for the treatment of patients with aluminum toxicity has been demonstrated to be clinically efficacious and is therefore regarded as a covered service.

C - Hemofiltration

This is a process which removes fluid, electrolytes and other low molecular weight toxic substances from the blood by filtration through hollow artificial membranes and may be routinely performed in 3 weekly sessions. Hemofiltration (which is also known as diafiltration) is a covered procedure under Medicare and is a safe and effective technique for the treatment of ESRD patients and an alternative to peritoneal dialysis and hemodialysis. In contrast to both hemodialysis and peritoneal dialysis treatments which eliminate dissolved substances via diffusion across semipermeable membranes, hemofiltration mimics the filtration process of the normal kidney. The technique requires an arteriovenous access. Hemofiltration may be performed either in facility or at home.

The procedure is most advantageous when applied to high-risk unstable patients, such as older patients with cardiovascular diseases or diabetes, because there are fewer side effects such as hypotension, hypertension or volume overload.

110.16 - Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation

(Rev. 1, 10-03-03)
CIM 35-71

Transplant surgeons have established a definite correlation in both cadaver and living-related kidney transplantation between pretransplant transfusions of blood into the recipient and the success of graft retention.

These pretransplant transfusions are covered under Medicare without a specific limitation on the number of transfusions, subject to the normal Medicare blood deductible provisions. Where blood is given directly to the transplant patient; e.g., in the case of donor specific transfusions, the blood is considered replaced for purposes of the blood deductible provisions. (See the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, “Deductibles, Coinsurance Amounts, and Payment Limitations,” §20.5.4.)

120 - Infectious Diseases
(Rev. 1, 10-03-03)

No coverage determinations

130 - Mental Health
(Rev. 1, 10-03-03)

130.1 - Inpatient Hospital Stays for the Treatment of Alcoholism
(Rev. 1, 10-03-03)
CIM 35-22

A - Inpatient Hospital Stay for Alcohol Detoxification

Many hospitals provide detoxification services during the more acute stages of alcoholism or alcohol withdrawal. When the high probability or occurrence of medical complications (e.g., delirium, confusion, trauma, or unconsciousness) during detoxification for acute alcoholism or alcohol withdrawal necessitates the constant availability of physicians and/or complex medical equipment found only in the hospital setting, inpatient hospital care during this period is considered reasonable and necessary and is therefore covered under the program. Generally, detoxification can be accomplished within two to three days with an occasional need for up to five days where the patient's condition dictates. This limit (five days) may be extended in an individual case where there is a need for a longer period for detoxification for a particular patient.

In such cases, however, there should be documentation by a physician which substantiates that a longer period of detoxification was reasonable and necessary. When the detoxification needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by §1862(a)(l) of the Act. Following detoxification a patient may be transferred to an inpatient rehabilitation unit or discharged to a residential treatment program or outpatient treatment setting.

B - Inpatient Hospital Stay for Alcohol Rehabilitation

Hospitals may also provide structured inpatient alcohol rehabilitation programs to the chronic alcoholic. These programs are composed primarily of coordinated educational and psychotherapeutic services provided on a group basis. Depending on the subject matter, a series of lectures, discussions, films, and group therapy sessions are led by either physicians, psychologists, or alcoholism counselors from the hospital or various outside organizations. In addition, individual psychotherapy and family counseling (see §70.1) may be provided in selected cases. These programs are conducted under the supervision and direction of a physician. Patients may directly enter an inpatient hospital rehabilitation program after having undergone detoxification in the same hospital or in

another hospital or may enter an inpatient hospital rehabilitation program without prior hospitalization for detoxification.

Alcohol rehabilitation can be provided in a variety of settings other than the hospital setting. In order for an inpatient hospital stay for alcohol rehabilitation to be covered under Medicare it must be medically necessary for the care to be provided in the inpatient hospital setting rather than in a less costly facility or on an outpatient basis. Inpatient hospital care for receipt of an alcohol rehabilitation program would generally be medically necessary where either (l) there is documentation by the physician that recent alcohol rehabilitation services in a less intensive setting or on an outpatient basis have proven unsuccessful and, as a consequence, the patient requires the supervision and intensity of services which can only be found in the controlled environment of the hospital, or (2) only the hospital environment can assure the medical management or control of the patient's concomitant conditions during the course of alcohol rehabilitation. (However, a patient's concomitant condition may make the use of certain alcohol treatment modalities medically inappropriate.) In addition, the "active treatment" criteria (see the Medicare Benefit Policy Manual, Chapter 2, "Inpatient Psychiatric Hospital Services," §20) should be applied to psychiatric care in the general hospital as well as to psychiatric care in a psychiatric hospital. Since alcoholism is classifiable as a psychiatric condition the "active treatment" criteria must also be met in order for alcohol rehabilitation services to be covered under Medicare. (Thus, it is the combined need for "active treatment" and for covered care which can only be provided in the inpatient hospital setting, rather than the fact that rehabilitation immediately follows a period of detoxification which provides the basis for coverage of inpatient hospital alcohol rehabilitation programs.)

Generally 16-19 days of rehabilitation services are sufficient to bring a patient to a point where care could be continued in other than an inpatient hospital setting. An inpatient hospital stay for alcohol rehabilitation may be extended beyond this limit in an individual case where a longer period of alcohol rehabilitation is medically necessary. In such cases, however, there should be documentation by a physician which substantiates the need for such care. Where the rehabilitation needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by §1862 (a)(l) of the Act.

Subsequent admissions to the inpatient hospital setting for alcohol rehabilitation follow-up, reinforcement, or "recap" treatments are considered to be readmissions (rather than an extension of the original stay) and must meet the requirements of this section for coverage under Medicare. Prior admissions to the inpatient hospital setting - either in the same hospital or in a different hospital - may be an indication that the "active treatment" requirements are not met (i.e., there is no reasonable expectation of improvement) and the stay should not be covered. Accordingly, there should be documentation to establish that "readmission" to the hospital setting for alcohol rehabilitation services can reasonably be expected to result in improvement of the patient's condition. For example, the documentation should indicate what changes in the patient's medical condition, social or

emotional status, or treatment plan make improvement likely, or why the patient's initial hospital treatment was not sufficient.

C - Combined Alcohol Detoxification/Rehabilitation Programs

Fiscal intermediaries should apply the guidelines in A. and B. above to both phases of a combined inpatient hospital alcohol detoxification/rehabilitation program. Not all patients who require the inpatient hospital setting for detoxification also need the inpatient hospital setting for rehabilitation. (See §130.1 for coverage of outpatient hospital alcohol rehabilitation services.) Where the inpatient hospital setting is medically necessary for both alcohol detoxification and rehabilitation, generally a 3-week period is reasonable and necessary to bring the patient to the point where care can be continued in other than an inpatient hospital setting.

Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by intermediaries based on accepted medical practice with the advice of their medical consultant. (In hospitals under PSRO review, PSRO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

130.2 - Outpatient Hospital Services for Treatment of Alcoholism

(Rev. 1, 10-03-03)
CIM 35-22

Some hospitals also provide services on an outpatient basis, either individually or as part of a day hospitalization program, for treatment of alcoholism. These services may include, for example, drug therapy, psychotherapy, and patient education and may be furnished by physicians, psychologists, nurses, and alcoholism counselors to individuals who have been discharged from an inpatient hospital stay for treatment of alcoholism and require continued treatment or to individuals from the community who require treatment but do not require the inpatient hospital setting.

Coverage is available for both diagnostic and therapeutic services furnished for the treatment of alcoholism by the hospital to outpatients subject to the same rules applicable to outpatient hospital services in general (see the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20). While there is no coverage for day hospitalization programs, per se, individual services which meet the requirements in the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20 may be covered. (Meals, transportation, and recreational and social activities do not fall within the scope of covered outpatient hospital services under Medicare.)

All services must be reasonable and necessary for diagnosis or treatment of the patient's condition (see the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20). Thus, educational services and family counseling would only be

covered where they are directly related to treatment of the patient's condition. (See also §70.1.) The frequency of treatment and period of time over which it occurs must also be reasonable and necessary.

130.3 - Chemical Aversion Therapy for Treatment of Alcoholism

(Rev. 1, 10-03-03)
CIM 35-23

Chemical aversion therapy is a behavior modification technique that is used in the treatment of alcoholism. Chemical aversion therapy facilitates alcohol abstinence through the development of conditioned aversions to the taste, smell, and sight of alcohol beverages. This is accomplished by repeatedly pairing alcohol with unpleasant symptoms (e.g., nausea) which have been induced by one of several chemical agents. While a number of drugs have been employed in chemical aversion therapy, the three most commonly used are emetine, apomorphine, and lithium. None of the drugs being used, however, have yet been approved by the Food and Drug Administration specifically for use in chemical aversion therapy for alcoholism. Accordingly, when these drugs are being employed in conjunction with this therapy, patients undergoing this treatment need to be kept under medical observation.
Available evidence indicates that chemical aversion therapy may be an effective component of certain alcoholism treatment programs, particularly as part of multi-modality treatment programs which include other behavioral techniques and therapies, such as psychotherapy. Based on this evidence, CMS's medical consultants have recommended that chemical aversion therapy be covered under Medicare. However, since chemical aversion therapy is a demanding therapy which may not be appropriate for all Medicare beneficiaries needing treatment for alcoholism, a physician should certify to the appropriateness of chemical aversion therapy in the individual case. Therefore, if chemical aversion therapy for treatment of alcoholism is determined to be reasonable and necessary for an individual patient, it is covered under Medicare.

When it is medically necessary for a patient to receive chemical aversion therapy as a hospital inpatient, coverage for care in that setting is available. (See §130.1 regarding coverage of multi-modality treatment programs.) Follow-up treatments for chemical aversion therapy can generally be provided on an outpatient basis. Thus, where a patient is admitted as an inpatient for receipt of chemical aversion therapy, there must be documentation by the physician of the need in the individual case for the inpatient hospital admission.

Decisions regarding reasonableness and necessity of treatment and the need for an inpatient hospital level of care should be made by intermediaries based on accepted medical practice with the advice of their medical consultant. (In hospitals under QIO review, QIO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

130.4 - Electrical Aversion Therapy for Treatment of Alcoholism

(Rev. 1, 10-03-03)
CIM 35-23.1

Electroversion Therapy, Electro-shock Therapy, Noxious Faradic Stimulation.
Electrical aversion therapy is a behavior modification technique to foster abstinence from ingestion of alcoholic beverages by developing in a patient conditioned aversions to their taste, smell and sight through electric stimulation. Electrical aversion therapy has not been shown to be safe and effective and therefore is excluded from coverage. (See also §§130.1, 130.3, and 30.1).

130.5 - Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic

(Rev. 1, 10-03-03)
CIM 35-22.3

Coverage is available for alcoholism or drug abuse treatment services (such as drug therapy, psychotherapy, and patient education) that are provided incident to a physicians professional service in a freestanding clinic to patients who, for example, have been discharged from an inpatient hospital stay for the treatment of alcoholism or drug abuse or to individuals who are not in the acute stages of alcoholism or drug abuse but require treatment. The coverage available for these services is subject to the same rules generally applicable to the coverage of clinic services. (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.1; the Medicare Claims Processing Manual, Chapter 12, "Physician/Practitioners Billing," §10; the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30. Of course, the services also must be reasonable and necessary for the diagnosis or treatment of the individual's alcoholism or drug abuse. The Part B psychiatric limitation (see the Medicare General Information, Eligibility, and Entitlement Manual,Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30) would apply to alcoholism or drug abuse treatment services furnished by physicians to individuals who are not hospital inpatients.

130.6 - Treatment of Drug Abuse (Chemical Dependency)

(Rev. 1, 10-03-03)
CIM 35-22.2

The CMS recognizes that there are similarities between the approach to treatment of drug abuse and alcohol detoxification and rehabilitation. However, the intensity and duration of treatment for drug abuse may vary (depending on the particular substance(s) of abuse, duration of use, and the patient's medical and emotional condition) from the duration of treatment or intensity needed to treat alcoholism. Accordingly, when it is medically necessary for a patient to receive detoxification and/or rehabilitation for drug substance abuse as a hospital inpatient, coverage for care in that setting is available. Coverage is also available for treatment services that are provided in the outpatient department of a

hospital to patients who, for example, have been discharged from an inpatient stay for the treatment of drug substance abuse or who require treatment but do not require the availability and intensity of services found only in the inpatient hospital setting. The coverage available for these services is subject to the same rules generally applicable to the coverage of outpatient hospital services. (See the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20). The services must also be reasonable and necessary for treatment of the individual's condition. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §90.) Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by intermediaries based on accepted medical practice with the advice of their medical consultant. (In hospitals under QIO review, QIO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

130.7 - Withdrawal Treatments for Narcotic Addictions

(Rev. 1, 10-03-03)
CIM 35-42

Withdrawal is an accepted treatment for narcotic addiction, and Part B payment can be made for these services if they are provided by the physician directly or under his personal supervision and if they are reasonable and necessary. In reviewing claims, reasonableness and necessity are determined with the aid of the contractor's medical staff.
Drugs that the physician provides in connection with this treatment are also covered if they cannot be self-administered and meet all other statutory requirements.

Cross-reference:

Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1.

130.8 - Hemodialysis for Treatment of Schizophrenia

(Rev. 1, 10-03-03)
CIM 35-51

Not Covered

Scientific evidence supporting use of hemodialysis as a safe and effective means of treatment for schizophrenia is inconclusive at this time. Accordingly, Medicare does not cover hemodialysis for treatment of schizophrenia.

140 - Miscellaneous Surgical Procedures
(Rev. 1, 10-03-03)

140.1 - Abortion
(Rev. 1, 10-03-03)
CIM 35-99

Abortions are not covered Medicare procedures except:

1 - If the pregnancy is the result of an act of rape or incest; or

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

This restricted coverage applies to CPT codes 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857, and 59866.

140.2 - Breast Reconstruction Following Mastectomy
(Rev. 1, 10-03-03)
CIM 35-47

During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

- A change in epidemiology of breast cancer, including an apparent increase in incidence;
- Improved surgical skills and techniques;
- The continuing development of better prostheses; and
- Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.
Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §1862(a)(10) of the Act.)

140.3 - Transsexual Surgery

(Rev. 1, 10-03-03)
CIM 35-61

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy which may be followed by phalloplasty and the insertion of testicular prostheses. Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

140.4 - Plastic Surgery to Correct "Moon Face"

(Rev. 1, 10-03-03)
CIM 35-12

Not Covered

The cosmetic surgery exclusion precludes payment for any surgical procedure directed at improving appearance. The condition giving rise to the patient's preoperative appearance is generally not a consideration. The only exception to the exclusion is surgery for the prompt repair of an accidental injury or for the improvement of a malformed body member which coincidentally serves some cosmetic purpose. Since surgery to correct a condition of "moon face" which developed as a side effect of cortisone therapy does not meet the exception to the exclusion, it is not covered under Medicare (§1862(a)(10) of the Act).

Cross reference: The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §120

140.5 - Laser Procedures

(Rev. 1, 10-03-03)
CIM 35-52

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to

determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

150 - Musculoskeletal System

(Rev. 1, 10-03-03)

150.1 - Manipulation

(Rev. 1, 10-03-03)
CIM 35-2

A - Manipulation of the Rib Cage

Manual manipulation of the rib cage contributes to the treatment of respiratory conditions such as bronchitis, emphysema, and asthma as part of a regimen that includes other elements of therapy, and is covered only under such circumstances.

B - Manipulation of the Head

Manipulation of the occipitocervical or temporomandibular regions of the head when indicated for conditions affecting those portions of the head and neck is a covered service.

150.2 - Osteogenic Stimulator

(Rev. 1, 10-03-03)
CIM 35-48

Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

Noninvasive Stimulator

The noninvasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Failed fusion, where a minimum of nine months has elapsed since the last surgery;
- Congenital pseudarthroses; and

As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc).
Invasive (Implantable) Stimulator

The invasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).
- Nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only after 6 or more months have elapsed without healing of the fracture.
- Nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Ultrasonic Osteogenic Stimulators

An ultrasonic osteogenic stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound, conductive gel in order to stimulate fracture healing. Ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of non-union fractures. In demonstrating nonunion of fractures, CMS would expect:

1 - A minimum of two sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

2 - Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

Nonunions of the skull, vertebrae, and those that are tumor-related are excluded from coverage.

The ultrasonic osteogenic stimulator may not be used concurrently with other noninvasive osteogenic devices. The national noncoverage policy related to ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains in place. This policy relates only to non-union as defined above.

150.3 - Bone (Mineral) Density Studies

(Rev. 1, 10-03-03)
CIM 50-44 NMES

Bone (mineral) density studies are used to evaluate diseases of bone and/or the responses of bone diseases to treatment. The studies assess bone mass or density associated with such diseases as osteoporosis, osteomalacia, and renal osteodystrophy. Various single or combined methods of measurement may be required to: (a) diagnose bone disease, (b) monitor the course of bone changes with disease progression, or (c) monitor the course of bone changes with therapy. Bone density is usually studied by using photodensitometry, single or dual photon absorptiometry, or bone biopsy.

The Following Bone (Mineral) Density Studies Are Covered Under Medicare

A - Single Photon Absorptiometry

A noninvasive radiological technique that measures absorption of a monochromatic photon beam by bone material. The device is placed directly on the patient, uses a low dose of radionuclide, and measures the mass absorption efficiency of the energy used. It provides a quantitative measurement of the bone mineral of cortical and trabecular bone, and is used in assessing an individual's treatment response at appropriate intervals. Single photon absorptiometry is covered under Medicare when used in assessing changes in bone density of patients with osteodystrophy or osteoporosis when performed on the same individual at intervals of 6 to 12 months.

B - Bone Biopsy

A physiologic test which is a surgical, invasive procedure. A small sample of bone (usually from the ilium) is removed, generally by a biopsy needle. The biopsy sample is then examined histologically, and provides a qualitative measurement of the bone mineral of trabecular bone. This procedure is used in ascertaining a differential diagnosis of bone disorders and is used primarily to differentiate osteomalacia from osteoporosis.

Bone biopsy is covered under Medicare when used for the qualitative evaluation of bone no more than four times per patient, unless there is special justification given. When used more than four times on a patient, bone biopsy leaves a defect in the pelvis and may produce some patient discomfort.

C - Photodensitometry (radiographic absorptiometry)

A noninvasive radiological procedure that attempts to assess bone mass by measuring the optical density of extremity radiographs with a photodensitometer, usually with a reference to a standard density wedge placed on the film at the time of exposure. This procedure provides a quantitative measurement of the bone mineral of cortical bone, and is used for monitoring gross bone change.

The Following Bone (Mineral) Density Study Is Not Covered Under Medicare:

D - Dual Photon Absorptiometry

A noninvasive radiological technique that measures absorption of a dichromatic beam by bone material. This procedure is not covered under Medicare because it is still considered to be in the investigational stage.

150.4 - Neuromuscular Electrical Stimulator (NMES) in the Treatment of Disuse Atrophy

(Rev. 1, 10-03-03)
CIM 35-77

Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. Coverage of NMES is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord, and peripheral nerves, and other non-neurological reasons for disuse are causing atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of NMES.)

150.5 - Diathermy Treatment

(Rev. 1, 10-03-03)
CIM 35-41

High energy pulsed wave diathermy machines have been found to produce some degree of therapeutic benefit for essentially the same conditions and to the same extent as standard diathermy. Accordingly, where the contractor's medical staff has determined that the pulsed wave diathermy apparatus used is one which is considered therapeutically effective, the treatments are considered a covered service, but only for those conditions for which standard diathermy is medically indicated and only when rendered by a physician or incident to a physician's professional services. (CPT-4 code 97024, ICD-9-CM code 93.34).

Cross-reference: §240.3.

150.6 - Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot

(Rev. 1, 10-03-03)
CIM 45-4

Not Covered

Vitamin B12 injections to strengthen tendons, ligaments, etc., of the foot are not covered under Medicare because (1) there is no evidence that vitamin B12 injections are effective for the purpose of strengthening weakened tendons and ligaments, and (2) this is nonsurgical treatment under the subluxation exclusion. Accordingly, vitamin B12 injections are not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

Cross reference:

The Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §30.
The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §100.

150.7 - Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents

(Rev. 1, 10-03-03)
CIM 35-13

Not Covered

The medical effectiveness of the above therapies has not been verified by scientifically controlled studies. Accordingly, reimbursement for these modalities should be denied on the ground that they are not reasonable and necessary as required by §1862(a)(1) of the Act.

150.8 - Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders

(Rev. 1, 10-03-03)
CIM 35-56

Fluidized therapy is a high intensity heat modality consisting of a dry whirlpool of finely divided solid particles suspended in a heated air stream, the mixture having the properties of a liquid. Use of fluidized therapy dry heat is covered as an acceptable alternative to other heat therapy modalities in the treatment of acute or subacute traumatic or nontraumatic musculoskeletal disorders of the extremities.

150.9 - Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee (Effective June 11, 2004)

(Rev. 14, 06-10-04)

Arthroscopy is a surgical procedure that allows the direct visualization of the interior joint space. In addition to providing visualization, arthroscopy enables the process of joint cleansing through the use of lavage or irrigation. Lavage alone may involve either large or small volume saline irrigation of the knee by arthroscopy. Although generally performed to reduce pain and improve function, current practice does not recognize the benefit of lavage alone for the reduction of mechanical symptoms. Arthroscopy also permits the removal of any loose bodies from the interior joint space, a procedure termed debridement. Debridement, when used alone or not otherwise specified, may include low volume lavage or washout. Osteoarthritis is a chronic and painful joint disease caused by degeneration. The American College of Rheumatology defines a patient diagnosis of osteoarthritis of the knee as presenting with pain, and meeting at least 5 of the following criteria:

- *Over 50 years of age;*
- *Less than 30 minutes of morning stiffness;*
- *Crepitus (noisy, grating sound) on active motion;*
- *Bony tenderness;*
- *Bony enlargement;*
- *No palpable warmth of synovium;*
- *ESR <40mm/hr;*
- *Rheumatoid Factor <1:40; or,*
- *Synovial fluid signs.*

A. Nationally Covered Indications

Not applicable.

B. Nationally Noncovered Indications

The clinical effectiveness of arthroscopic lavage and arthroscopic debridement for the severe osteoarthritic knee has not been verified by scientifically controlled studies. After thorough discussions with clinical investigators, the orthopedic community, and other interested parties, CMS determines that the following procedures are not considered reasonable or necessary in treatment of the osteoarthritic knee and are not covered by the Medicare program:

Arthroscopic lavage used alone for the osteoarthritic knee;

- *Arthroscopic debridement for osteoarthritic patients presenting with knee pain only; or,*

- *Arthroscopic debridement and lavage with or without debridement for patients presenting with severe osteoarthritis ((Severe osteoarthritis is defined in the Outerbridge classification scale, grades III and IV. Outerbridge is the most*

commonly used clinical scale that classifies the severity of joint degeneration of the knee by compartments and grades. Grade I is defined as softening or blistering of joint cartilage. Grade II is defined as fragmentation or fissuring in an area <1 cm. Grade III presents clinically with cartilage fragmentation or fissuring in an area >1 cm. Grade IV refers to cartilage erosion down to the bone. Grades III and IV are characteristic of severe osteoarthritis.)

C. Other

Apart from the noncovered indications above for arthroscopic lavage and/or arthroscopic debridement of the osteoarthritic knee, all other indications of debridement for the subpopulation of patients without severe osteoarthritis of the knee who present with symptoms other than pain alone; i.e., (1) mechanical symptoms that include, but are not limited to, locking, snapping, or popping (2) limb and knee joint alignment, and (3) less severe and/or early degenerative arthritis, remain at local contractor discretion. Medicare contractors may require submission of one or all of the following documents to define the patient's knee condition:

- *Operative notes,*
- *Reports of standing x-rays, or,*
- *Arthroscopy results.*

(This NCD last reviewed June 2004.)

160 - Nervous System

(Rev. 1, 10-03-03)

160.1 - Induced Lesions of Nerve Tracts

(Rev. 1, 10-03-03)
CIM 35-17

Surgically induced lesions of nerve tracts which involve destruction of nerve tissue, are primarily indicated for controlling the chronic or acute pain arising from conditions such as terminal cancer or lumbar degenerative arthritis. Induced lesions of nerve tracts may be produced by surgical cutting of the nerve (rhizolysis), chemical destruction of the nerve, or by creation of a radio-frequency lesion (electrocautery). Accordingly, program payment may be made for these denervation procedures when used in selected cases (concurred in by contractor's medical staff) to treat chronic pain.

Note that these procedures differ from those employing implanted electrodes and associated equipment to control pain in that the nerve fibers are ablated rather than stimulated and no electronic equipment is required by the patient after the operation.

160.2 - Treatment of Motor Function Disorders with Electric Nerve Stimulation

(Rev. 1, 10-03-03)
CIM 35-20

Not Covered

While electric nerve stimulation has been employed to control chronic intractable pain for some time, its use in the treatment of motor function disorders, such as multiple sclerosis, is a recent innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary. See §§30.1 and 160.7.

NOTE: For Medicare coverage of deep brain stimulation for essential tremor and Parkinson's disease, see §160.25.

160.3 - Assessing Patients Suitability for Electrical Nerve Stimulation

(Rev. 1, 10-03-03)
CIM 35-46

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A - Transcutaneous Electrical Nerve Stimulation (TENS)

This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services that are furnished beyond the first month. (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

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

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

B - Percutaneous Electrical Nerve Stimulation (PENS)

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

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

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.8 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §230.15 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

160.4 - Steroetactic Cingulotomy as a Means of Psychosurgery

(Rev. 1, 10-03-03)
CIM 35-84

Not Covered

Cingulotomy is a psychosurgical procedure designed to interrupt the interconnecting neuronal pathways of the brain involved in the regulation of the emotions and certain autonomic functions. The intent of psychosurgery is to modify or alter disturbances of behavior, thought content, or mood that are not responsive to other conventional modes of therapy, or for which no organic pathological cause can be demonstrated by established methods.

The operation usually involves bilateral lesions that are placed in the anterior cingulum of the brain. Electrocautery probes are stereotactically inserted through lateral burr holes in the skull. A radio frequency pulsating current is used to ablate the tissue that connects the limbic system to the frontal lobe. Two or three repeat procedures may be performed in the same patient when a satisfactory result has not been achieved with the first cingulotomy.

Stereotactic cingulotomy is not covered under Medicare because the procedure is considered to be investigational.

160.5 - Steroetaxic Depth Electrode Implantation

(Rev. 1, 10-03-03)
CIM 50-40

Stereotaxic depth electrode implantation prior to surgical treatment of focal epilepsy for patients who are unresponsive to anticonvulsant medications has been found both safe and effective for diagnosing resectable seizure foci that may go undetected by conventional scalp electroencephalographs (EEGs).

The procedure employs thin wire electrodes which are implanted in the brain of the focal epileptic patient for EEG monitoring. By taking several readings during seizure activity, the location of the epileptic focus may be found, so that better informed decisions can be made regarding the surgical treatment of persons with intractable seizures.

160.6 - Carotid Sinus Nerve Stimulator

(Rev. 1, 10-03-03)
CIM 65-4

Implantation of the carotid sinus nerve stimulator is indicated for relief of angina pectoris in carefully selected patients who are refractory to medical therapy and who after undergoing coronary angiography study either are poor candidates for or refuse to have coronary bypass surgery. In such cases, Medicare reimbursement may be made for this device and for the related services required for its implantation.

However, the use of the carotid sinus nerve stimulator in the treatment of paroxysmal supraventricular tachycardia is considered investigational and is not in common use by the medical community. The device and related services in such cases cannot be considered as 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.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Services," §120

The Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §40 and §120.

160.7 - Electrical Nerve Stimulators

(Rev. 1, 10-03-03)
CIM 65-8

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A - Implanted Peripheral Nerve Stimulators

Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch.

Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in §160.7.1, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B - Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators)

The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1 - Types of Implantations

There are two types of implantations covered by this instruction:

- Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.

- Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2 - Conditions for Coverage

No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
- With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
- Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy item c) must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Contractors may find it helpful to work with Quality Improvement Organizatins (QIOs) to obtain the information needed to apply these conditions to claims.

See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §120, and the following sections in this manual, §§160.2 and 30.1.

160.7.1 - Assessing Patients Suitability for Electrical Nerve Stimulation Therapy

(Rev. 1, 10-03-03)
CIM 35-46

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

Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:
A - Transcutaneous Electrical Nerve Stimulation (TENS)

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

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain. (See §160.3.)

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

B - Percutaneous Electrical Nerve Stimulation (PENS)

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

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

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment

of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.7 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §280.13 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

160.8 - Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature

(Rev. 1, 10-03-03)
CIM 35-57

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

The EEG monitoring may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted. Electroencephalographic (EEG) monitoring during open-heart surgery - Not covered The value of EEG monitoring during open heart surgery and in the immediate post-operative period is debatable because there is little published data, based on well designed studies, regarding its clinical effectiveness. The procedure is not frequently used and does not enjoy widespread acceptance of benefit.

Accordingly, Medicare does not cover EEG monitoring during open heart surgery and during the immediate post-operative period.

160.9 – Electroencephalographic (EEG) Monitoring During Open-Heart Surgery

(Rev. 1, 10-03-03)
CIM 35-57.1

Not Covered

The value of EEG monitoring during open heart surgery and in the immediate post-operative period is debatable because there are little published data based on well

designed studies regarding its clinical effectiveness. The procedure is not frequently used and does not enjoy widespread acceptance of benefit.

Accordingly, Medicare does not cover EEG monitoring during open heart surgery and during the immediate post-operative period.

160.10 - Evoked Response Tests

(Rev. 1, 10-03-03)
CIM 50-31

Evoked response tests, including brain stem evoked response and visual evoked response tests, are generally accepted as safe and effective diagnostic tools. These tests measure brain responses to repetitive visual, click or other stimuli. Program payment may be made for these procedures.

160.11 - Osteogenic Stimulator

(Rev. 1, 10-03-03)
CIM 35-48

Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

1 - Noninvasive Stimulator

The noninvasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Failed fusion, where a minimum of nine months has elapsed since the last surgery;
- Congenital pseudarthroses; and
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

2 - Invasive (Implantable) Stimulator

The invasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures; and
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1).

Nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only after six or more months have elapsed without healing of the fracture.

Nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

B - Ultrasonic Osteogenic Stimulators

An ultrasonic osteogenic stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound, using conductive gel, in order to stimulate fracture healing. Ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of non-union fractures. In demonstrating nonunion of fractures, CMS would expect :

- A minimum of two sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph must include multiple views of the fracture site, accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

- Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

Non-unions of the skull, vertebrae, and those that are tumor-related are excluded from coverage. The ultrasonic osteogenic stimulator may not be used concurrently with other noninvasive osteogenic devices. The national noncoverage policy related to ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains in place. This policy relates only to non-union as defined above.

160.12 - Neuromuscular Electrical Stimulator (NMES)

(Rev. 1, 10-03-03)
CIM 35-77

Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of

electrodes. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients.

Treatment of Muscle Atrophy

Coverage of NMES to treat muscle atrophy is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of NMES.)

Use for Walking in Patients with Spinal Cord Injury (SCI)

The type of NMES that is use to enhance the ability to walk of SCI patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence. Coverage for the use of NMES/FES is limited to SCI patients for walking, who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months. The trial period of physical therapy will enable the physician treating the patient for his or her spinal cord injury to properly evaluate the person's ability to use these devices frequently and for the long term. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program. .

The goal of physical therapy must be to train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy.

Coverage for NMES/FES for walking will be covered in SCI patients with all of the following characteristics:

1. Persons with intact lower motor unite (L1 and below) (both muscle and peripheral nerve);

2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;

3. Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;

4. Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

5. Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;

6. Persons that can demonstrate hand and finger function to manipulate controls;

7. Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
8. Persons with hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and

9. Persons who have demonstrated a willingness to use the device long-term.

NMES/FES for walking will not be covered in SCI patient with any of the following:

1. Persons with cardiac pacemakers;

2. Severe scoliosis or severe osteoporosis;

3. Skin disease or cancer at area of stimulation;

4. Irreversible contracture; or

5. Autonomic dysflexia.

The only settings where therapists with the sufficient skills to provide these services are employed, are inpatient hospitals; outpatient hospitals; comprehensive outpatient rehabilitation facilities; and outpatient rehabilitation facilities. The physical therapy necessary to perform this training must be part of a one-on-one training program.

Additional therapy after the purchase of the DME would be limited by our general policies in converge of skilled physical therapy.

(Also reference the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §230, and the Medicare Claims Processing Manual, Chapter 5, "Part B Outpatient Rehabilitation and CORF Services," §10.1)

160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)

(Rev. 1, 10-03-03)
CIM 45-25

Transcutaneous Electrical Nerve Stimulation (TENS) and/or Neuromuscular Electrical Stimulation (NMES) can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients' skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

1 - It has received permission or approval for marketing by the Food and Drug Administration;

2 - It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and

3 - One of the medical indications outlined below is met:

- The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
- The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
- The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
- The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or
- The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §160.3 unless:

4 - The patient has a documented skin problem prior to the start of the trial period; and

5 - The carrier's medical consultants are satisfied that use of such an item is medically necessary for the patient.

(See conditions for coverage of the use of TENS in the diagnosis and treatment of chronic intractable pain in §§160.3 and 160.13 and the use of NMES in the treatment of disuse atrophy in §150.4.)

160.14 - Invasive Intracranial Pressure Monitoring

(Rev. 1, 10-03-03)
CIM 35-62

Invasive intracranial pressure monitoring is a safe and effective therapeutic tool used to monitor intracranial pressure. It is usually used for patients suffering from head injuries,

subarachnoid hemorrhage, intracerebral hemorrhage, Reye's syndrome, or posthypoxic, metabolic, and viral encephalopathies. It is usually performed in specialized intensive care units for neurosurgical and neurologic patients. It is a covered procedure when reasonable and necessary for the individual patient.

160.15 - Electrotherapy for Treatment of Facial Nerve Palsy (Bell's Palsy)

(Rev. 1, 10-03-03)
CIM 35-72

Not Covered

Electrotherapy for the treatment of facial nerve paralysis is the application of electrical stimulation to affected facial muscles to provide muscle innervation with the intention of preventing muscle degeneration. A device that generates an electrical current with controlled frequency, intensity, wave form and type (galvanic or faradic) is used in combination with a pad electrode and a hand applicator electrode to provide electrical stimulation.

Electrotherapy for the treatment of facial nerve paralysis, commonly known as Bell's Palsy, is not covered under Medicare because its clinical effectiveness has not been established.

160.16 - Vertebral Axial Decompression (VAX-D)

(Rev. 1, 10-03-03)
CIM 35-97

Not Covered

Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disk problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.

160.17 - L-Dopa

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

A - Part A Payment for L-Dopa and Associated Inpatient Hospital Service

A hospital stay and related ancillary services for the administration of L-Dopa are covered if medically required for this purpose. Whether a drug represents an allowable inpatient hospital cost during such stay depends on whether it meets the definition of a drug in §1861(t) of the Act; i.e., on its inclusion in the compendia named in the Act or approval by the hospital's pharmacy and drug therapeutics (P&DT) or equivalent

committee. (Levodopa (L-Dopa) has been favorably evaluated for the treatment of Parkinsonism by A.M.A. Drug Evaluations, First Edition 1971, the replacement compendia for “New Drugs.")

Inpatient hospital services are frequently not required in many cases when L-Dopa therapy is initiated. Therefore, determine the medical need for inpatient hospital services on the basis of medical facts in the individual case. It is not necessary to hospitalize the typical, well-functioning, ambulatory Parkinsonian patient who has no concurrent disease at the start of L-Dopa treatment. It is reasonable to provide inpatient hospital services for Parkinsonian patients with concurrent diseases, particularly of the cardiovascular, gastrointestinal, and neuropsychiatric systems. Although many patients require hospitalization for a period of under two weeks, a 4-week period of inpatient care is not unreasonable.

Laboratory tests in connection with the administration of L-Dopa - The tests medically warranted in connection with the achievement of optimal dosage and the control of the side effects of L-Dopa include a complete blood count, liver function tests such as SGOT, SGPT, and/or alkaline phosphatase, BUN or creatinine and urinalysis, blood sugar, and electrocardiogram.

Whether or not the patient is hospitalized, laboratory tests in certain cases are reasonable at weekly intervals although some physicians prefer to perform the tests much less frequently.

Physical therapy furnished in connection with administration of L-Dopa - Where, following administration of the drug, the patient experiences a reduction of rigidity which permits the reestablishment of a restorative goal for him/her, physical therapy services required to enable him/her to achieve this goal are payable provided they require the skills of a qualified physical therapist and are furnished by or under the supervision of such a therapist. However, once the individual’s restoration potential has been achieved, the services required to maintain him/her at this level do not generally require the skills of a qualified physical therapist. In such situations, the role of the therapist is to evaluate the patient’s needs in consultation with his/her physician and design a program of exercise appropriate to the capacity and tolerance of the patient and treatment objectives of the physician, leaving to others the actual carrying out of the program. While the evaluative services rendered by a qualified physical therapist are payable as physical therapy, services furnished by others in connection with the carrying out of the maintenance program established by the therapist are not. (See the Medicare Benefit Policy Manual, Chapter 1, “Inpatient Hospital Services,” §30.)

B - Part A Reimbursement for L-Dopa Therapy in SNFs

Initiation of L-Dopa therapy can be appropriately carried out in the skilled nursing facility (SNF) setting, applying the same guidelines used for initiation of L-Dopa therapy in the hospital, including the types of patients who should be covered for inpatient services, the role of physical therapy, and the use of laboratory tests. (See subsection A.)

Where inpatient care is required and L-Dopa therapy is initiated in the SNF, limit the stay to a maximum of four weeks; but in many cases the need may be no longer than one or two weeks, depending upon the patient's condition. However, where L-Dopa therapy is begun in the hospital and the patient is transferred to a SNF for continuation of the therapy, a combined length of stay in hospital and SNF of no longer than four weeks is reasonable (i.e., 1-week hospital stay followed by three weeks SNF stay; or two weeks hospital stay followed by two weeks SNF stay; etc.). Medical need must be demonstrated in cases where the combined length of stay in hospital and SNF is longer than four weeks. The choice of hospital or SNF, and the decision regarding the relative length of time spent in each, should be left to the medical judgment of the treating physician. See the Medicare Benefit Policy Manual, Chapter 8, "Coverage of Extended Care (SNF) Services Under Hospital Insurance," §50.5.

C - L-Dopa Coverage Under Part B

Part B reimbursement may not be made for the drug L-Dopa since it is a self-administrable drug. (See the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1.) However, physician services rendered in connection with its administration and control of its side effects are covered if determined to be reasonable and necessary. Initiation of L-Dopa therapy on an outpatient basis is possible in most cases. Visit frequency ranging from every week to every 2 or 3 months is acceptable. However, after half a year of therapy, visits more frequent than every month would usually not be reasonable.

160.18 - Vagus Nerve Stimulation for Treatment of Seizures

(Rev. 1, 10-03-03)
CIM 60-22

In the past 10 years, there have been significant advances in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, 25-50 percent of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs.

The vagus nerve is a mixed nerve carrying both somatic and visceral afferent and efferent signals. The majority of vagal nerve fibers are visceral afferents with wide distribution. The basic premise of vagus nerve stimulation in the treatment of epilepsy is that vagal visceral afferents have a diffuse central nervous system projection and the activation of these pathways has a widespread effect upon neuronal excitability. Besides activation of well-defined reflexes, vagal stimulation produces evoked potentials recorded from the cerebral cortex, the hippocampus, the thalamus, and the cerebellum.

The vagus nerve stimulation system is comprised of an implantable pulse generator and lead and an external programming system used to change stimulation settings. Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. Vagus nerve stimulation is not covered

for patients with other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.
A partial onset seizure has a focal onset in one area of the brain and may or may not involve a loss of motor control or alteration of consciousness. Partial onset seizures may be simple, complex, or complex partial seizures, secondarily generalized.

Cross reference to §160, "Electrical Nerve Stimulators."

160.19 - Phrenic Nerve Stimulator

(Rev. 1, 10-03-03)
CIM 65-13

The implantation of a phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency.

The phrenic nerve stimulator provides electrical stimulation of the patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs). The device has been used successfully to treat hypoventilation caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord and chronic pulmonary disease with ventilatory insufficiency. The phrenic nerve stimulator is intended to be an alternative to management of patients with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma.

However, an implanted phrenic nerve stimulator can be effective only if the patient has an intact phrenic nerve and diaphragm. Moreover, nerve injury may occur during the surgical procedure and if sufficient injury is incurred, the device will not prove useful to the patient. Consequently, it is possible for such a device to be indicated for a patient but, due to injury sustained during implant, fail to assist the patient, resulting in a return to the use of mechanical ventilation.

Cross reference to §160.7, "Electrical Nerve Stimulators."

160.20 - Transfer Factor for Treatment of Multiple Sclerosis

(Rev. 1, 10-03-03)
CIM 45-17

Transfer factor is the dialysate of an extract from sensitized leukocytes which increases cellular immune activity in the recipient. It is not covered as a treatment for multiple sclerosis because its use for the purpose is still experimental.

160.21 - Telephone Transmission of EEGs

(Rev. 1, 10-03-03)
CIM - 50-39

Telephone transmission of electroencephalograms (EEGs) is covered as a physician's service, or as incident to a physician's service when reasonable and necessary for the individual patient, under appropriate circumstances. The service is safe, and may save time and cost in sending EEGs from remote areas without special competence in neurology, neurosurgery, and electroencephalography, by avoiding the need to transport patients to large medical centers for standard EEG testing.

Telephone transmission of EEGs has been most helpful in the following clinical situations:

- Altered consciousness, such as stuporous, semicomatose, or comatose states;
- A typical seizure variants in patients experiencing bizarre, distressing symptoms as seen with "spike and wave stupor" or other forms of seizure disorders;
- Diagnosis of a suspected intracranial tumor;
- Head injury, where a subdural hematoma may be identified;
- Headaches during the acute phase where, for instance, in migraine syndrome, abnormal responses may be seen.

Telephonically transmitted EEGs should not be used for determining electrical inactivity (i.e., brain death), because of unavoidable signal interference.

160.22 - Ambulatory EEG Monitoring

(Rev. 1, 10-03-03)
CIM - 50-39.1

Ambulatory, or 24-hour electroencephalographic (EEG) monitoring is accomplished by a cassette recorder that continuously records brain wave patterns during 24 hours of a patient's routine daily activities and sleep. The monitoring equipment consists of an electrode set, preamplifiers, and a cassette recorder. The electrodes attach to the scalp, and their leads are connected to a recorder, usually worn on a belt.

Ambulatory EEG monitoring is a diagnostic procedure for patients in whom a seizure diathesis is suspected but not defined by history, physical or resting EEG. Ambulatory EEG can be utilized in the differential diagnosis of syncope and transient ischemic attacks if not elucidated by conventional studies. Ambulatory EEG should always be preceded by a resting EEG.

Ambulatory EEG monitoring is considered an established technique and covered under Medicare for the above purposes.

160.23 - Sensory Nerve Conduction Threshold Tests (sNCTs) (Effective April 1, 2004)

(Rev.15, 06-18-04)

A. General

The sNCT is a psychophysical assessment of both central and peripheral nerve functions. It measures the detection threshold of accurately calibrated sensory stimuli. This procedure is intended to evaluate and quantify function in both large and small caliber fibers for the purpose of detecting neurologic disease. Sensory perception and threshold detection are dependent on the integrity of both the peripheral sensory apparatus and peripheral-central sensory pathways. In theory, an abnormality detected by this procedure may signal dysfunction anywhere in the sensory pathway from the receptors, the sensory tracts, the primary sensory cortex, to the association cortex.

This procedure is different and distinct from assessment of nerve conduction velocity, amplitude and latency. It is also different from short-latency somatosensory evoked potentials.

Effective October 1, 2002, CMS initially concluded that there was insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law. \

Therefore, sNCT was noncovered.

Effective April 1, 2004, based on a reconsideration of current Medicare policy for sNCT, CMS concludes that the use of any type of sNCT device (e.g., “current output” type device used to perform current perception threshold (CPT), pain perception threshold (PPT), or pain tolerance threshold (PTT) testing or “voltage input” type device used for voltage-nerve conduction threshold (v-NCT) testing) to diagnose sensory neuropathies or radiculopathies in Medicare beneficiaries is not reasonable and necessary.

B. Nationally Covered Indications

Not applicable.

C. Nationally Noncovered Indications

All uses of sNCT to diagnose sensory neuropathies or radiculopathies are noncovered. (This NCD last reviewed June 2004.)

160.24 – Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease

(Rev. 1, 10-03-03)

CIM – 65-19

Effective for services furnished on or after April 1, 2003, Medicare will cover unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) for the treatment of essential tremor (ET) and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPi) DBS for the treatment of Parkinson's disease (PD) only under the following conditions:

1. Medicare will only consider DBS devices to be reasonable and necessary if they are Food and Drug Administration (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

2. For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

    a. Diagnosis of ET based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia)) which is of a tremor- dominant form.
    b. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.
    c. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

3. For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

    a. Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).
    b. Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
    c. L-dopa responsive with clearly defined "on" periods.
    d. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
    e. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

DBS is not reasonable and necessary and is not covered for ET or PD patients with any of the following:

1. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.

2. Cognitive impairment, dementia or depression whichwould be worsened by or would interfere with the patient's ability to benefit from DBS.

3. Current psychosis, alcohol abuse or other drug abuse.

Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.

Previous movement disorder surgery within the affected basal ganglion.

Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.

Patients who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI whichmay adversely affect the DBS system or adversely affect the brain around the implanted electrodes.

DBS should be performed with extreme caution in patients with cardiac pacemakers or other electronically controlled implants whichmay adversely affect or be affected by the DBS system.

For DBS lead implantation to be considered reasonable and necessary, providers and facilities must meet all of the following criteria:

Neurosurgeons must:

a. Be properly trained in the procedure;
b. Have experience with the surgical management of movement disorders, including DBS therapy; and
c. Have experience performing stereotactic neurosurgical procedures.

Operative teams must have training and experience with DBS systems, including knowledge of anatomical and neurophysiological characteristics for localizing the targeted nucleus, surgical and/or implantation techniques for the DBS system, and operational and functional characteristics of the device.

Physicians specializing in movement disorders must be involved in both patient selection and post-procedure care.

Hospital medical centers must have:

a. Brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s);
b. Operating rooms with all necessary equipment for stereotactic surgery; and

c. Support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively.

160.25 - Multiple Electroconvulsive Therapy (MECT)

(Rev. 1, 10-03-03)
CIM - 35-103

The clinical effectiveness of the multiple-seizure electroconvulsive therapy has not been verified by scientifically controlled studies. In addition, studies have demonstrated an increased risk of adverse effects with multiple seizures. Accordingly, MECT cannot be considered reasonable and necessary and is not covered by the Medicare program. Effective for services provided on or after April 1, 2003.