

50 DIAGNOSTIC SERVICES

50-1 CARDIAC PACEMAKER EVALUATION SERVICES (Effective for services rendered on or after October 1, 1984.)

Medicare covers a variety of services for the post-implant follow-up and evaluation of implanted cardiac pacemakers. The following guidelines are designed to assist contractors in identifying and processing claims for such services.

NOTE: These new guidelines are limited to lithium battery-powered pacemakers, because mercury-zinc battery-powered pacemakers are no longer being manufactured and virtually all have been replaced by lithium units. Contractors still receiving claims for monitoring such units should continue to apply the guidelines published in 1980 to those units until they are replaced.

There are two general types of pacemakers in current use--single-chamber pacemakers, which sense and pace the ventricles of the heart, and dual-chamber pacemakers which sense and pace both the atria and the ventricles. These differences require different monitoring patterns over the expected life of the units involved. One fact of which contractors should be aware is that many dual-chamber units may be programmed to pace only the ventricles; this may be done either at the time the pacemaker is implanted or at some time afterward. In such cases, a dual-chamber unit, when programmed or reprogrammed for ventricular pacing, should be treated as a single-chamber pacemaker in applying screening guidelines.

The decision as to how often any patient's pacemaker should be monitored is the responsibility of the patient's physician who is best able to take into account the condition and circumstances of the individual patient. These may vary over time, requiring modifications of the frequency with which the patient should be monitored. In cases where monitoring is done by some entity other than the patient's physician, such as a commercial monitoring service or hospital outpatient department, the physician's prescription for monitoring is required and should be periodically renewed (at least annually) to assure that the frequency of monitoring is proper for the patient. Where a patient is monitored both during clinic visits and transtelephonically, the contractor should be sure to include frequency data on both types of monitoring in evaluating the reasonableness of the frequency of monitoring services received by the patient.

Since there are over 200 pacemaker models in service at any given point, and a variety of patient conditions that give rise to the need for pacemakers, the question of the appropriate frequency of monitorings is a complex one. Nevertheless, it is possible to develop guidelines within which the vast majority of pacemaker monitorings will fall and contractors should do this, using their own data and experience, as well as the frequency guidelines which follow, in order to limit extensive claims development to those cases requiring special attention.

Guidelines for Transtelephonic Monitoring of Cardiac Pacemakers

A. General--Transtelephonic monitoring of pacemakers is coming into increasingly widespread use, with the services being furnished by commercial suppliers, hospital outpatient departments and physicians offices.

Telephone monitoring of cardiac pacemakers as described below is medically efficacious in identifying early signs of possible pacemaker failure, thus reducing the number of sudden pacemaker failures requiring emergency replacement. All systems which monitor the pacemaker rate (bpm) in both the free-running and/or magnetic mode are effective in detecting subclinical pacemaker failure due to battery depletion. More sophisticated systems are also capable of detecting internal electronic problems within the pulse generator itself and other potential problems. In the case of dual chamber pacemakers in particular, such monitoring may detect failure of synchronization of the atria and ventricles, and the need for adjustment and reprogramming of the device.

NOTE: The transmitting device furnished to the patient is simply one component of the diagnostic system, and is not covered as durable medical equipment. Those engaged in transtelephonic pacemaker monitoring should reflect the costs of the transmitters in setting their charges for monitoring.

B. Definition of Transtelephonic Monitoring--In order for transtelephonic monitoring services to be covered, the services must consist of the following elements:

1. A minimum 30-second readable strip of the pacemaker in the free-running mode;
2. Unless contraindicated, a minimum 30-second readable strip of the pacemaker in the magnetic mode; and
3. A minimum 30 seconds of readable ECG strip.

C. Frequency Guidelines for Transtelephonic Monitoring--The guidelines below constitute a system which contractors should use, in conjunction with their knowledge of local medical practices, to screen claims for transtelephonic monitoring prior to payment. It is important to note that they are not recommendations with respect to a minimum frequency for such monitorings, but rather a maximum frequency (within which payment may be made without further claims development). As with previous guidelines, more frequent monitorings may be covered in cases where contractors are satisfied that such monitorings are medically necessary; e.g., based on the condition of the patient, or with respect to pacemakers exhibiting unexpected defects or premature failure. Contractors should seek written justification for more frequent monitorings from the patient's physician and/or any monitoring service involved.

These guidelines are divided into two broad categories--Guideline I, which will apply to the majority of pacemakers now in use, and Guideline II, which will apply only to pacemaker systems (pacemaker and leads) for which sufficient long-term clinical information exists to assure that they meet the standards of the Inter-Society Commission for Heart Disease Resources (ICHD) for longevity and end-of-life decay. (The ICHD

standards are: (1) 90 percent cumulative survival at 5 years following implant; and (2) an end-of-life decay of less than a 50 percent drop of output voltage and less than 20 percent deviation of magnet rate, or a drop of 5 beats per minute or less, over a period of 3 months or more.) Contractors should consult with their medical advisers and other appropriate individuals and organizations (such as the North American Society of Pacing and Electrophysiology, which publishes product reliability information) should questions arise over whether a pacemaker system meets the ICHD standards.

The two groups of guidelines are then further broken down into two general categories--single chamber and dual-chamber pacemakers. Contractors should be aware that the frequency with which a patient is monitored may be changed from time to time for a number of reasons, such as a change in the patient's overall condition, a reprogramming of the patient's pacemaker, the development of better information on the pacemaker's longevity or failure mode, etc. Consequently, changes in the proper set of guidelines may be required. Contractors should inform physicians and monitoring services to alert contractors to any changes in the patient's monitoring prescription that might necessitate changes in the screening guidelines applied to that patient. (Of particular importance is the reprogramming of a dual-chamber pacemaker to a single-chamber mode of operation. Such reprogramming would shift the patient from the appropriate dual-chamber guideline to the appropriate single-chamber guideline.)

Guideline I

1. Single-chamber pacemakers:
1st month--every 2 weeks.
2nd through 36th month--every 8 weeks.
37th month to failure--every 4 weeks.
2. Dual-chamber pacemaker:
1st month--every 2 weeks.
2nd through 6th month--every 4 weeks.
7th through 36th month--every 8 weeks.
37th month to failure--every 4 weeks.

Guideline II

1. Single-chamber pacemakers:
1st month--every 2 weeks.
2nd through 48th month--every 12 weeks.
49th through 72nd month--every 8 weeks.
Thereafter--every 4 weeks.
2. Dual-chamber pacemaker:
1st month--every 2 weeks.
2nd through 30th month--every 12 weeks.
31st through 48th month--every 8 weeks.
Thereafter--every 4 weeks.

D. Pacemaker Clinic Services

1. General--Pacemaker monitoring is also covered when done by pacemaker clinics. Clinic visits may be done in conjunction with transtelephonic monitoring or as a separate service; however, the services rendered by a pacemaker clinic are more extensive than those currently possible by telephone. They include, for example, physical examination of patients and reprogramming of pacemakers. Thus, the use of one of these types of monitoring does not preclude concurrent use of the other.

2. Frequency Guidelines--As with transtelephonic pacemaker monitoring, the frequency of clinic visits is the decision of the patient's physician, taking into account, among other things, the medical condition of the patient. However, contractors can develop monitoring guidelines that will prove useful in screening claims. The following are recommendations for monitoring guidelines on lithium-battery pacemakers:

- a. For single-chamber pacemakers - twice in the first 6 months following implant, then once every 12 months.
- b. For dual-chamber pacemakers - twice in the first 6 months, then once every 6 months.

**50-2 CYTOTOXIC FOOD TESTS--NOT COVERED
(Effective for services performed on or after **August 5, 1985.**)**

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 HCFA Ruling in the Federal Register on July 5, 1985.

50-3 HIS BUNDLE STUDY

The His Bundle Study is a specialized type of electrocardiography requiring catheterization of the right side of the heart and is a recognized diagnostic procedure. Medicare coverage of the procedure would be limited to selected patients: those with complex ongoing acute arrhythmias, those with intermittent or permanent heart block in whom pacemaker implantation is being considered, and those patients who have recently developed heart block secondary to a myocardial infarction. When heart catheterization and the His Bundle Study are performed at the same time, the program will cover only one catheterization and a small additional charge for the study.

The following is effective for services performed on or after 12-03-84.

When a His bundle cardiogram is obtained as part of a diagnostic endocardial electrical stimulation, no separate charge will be recognized for the His bundle study. (See 35-78, Diagnostic Endocardial Electrical Stimulation.)

50-4 GRAVLEE JET WASHER

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

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

(See Intermediary Manual, §3157 and Carriers Manual, §2320.)

50-5 THERMOGRAPHY (Effective for services performed on and after December 21, 1992.)

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

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

50-6 PLETHYSMOGRAPHY

Plethysmography involves the measurement and recording (by one of several methods) of changes in the size of a body part as modified by the circulation of blood in that part. Plethysmography is of value as a noninvasive technique for diagnostic, preoperative and postoperative evaluation of peripheral artery disease in the internal medicine or vascular surgery practice. It is also a useful tool for the preoperative podiatric evaluation of the diabetic patient or one who has intermittent claudication or other signs or symptoms indicative of peripheral vascular disease which have a bearing on the patient's candidacy for foot surgery.

The oldest form of plethysmography is the venous occlusive pneumoplethysmography. This method is cumbersome, time consuming, and requires considerable training to give useful, reproducible results. Nonetheless, in the setting of the hospital vascular laboratory, this technique is considered a reasonable and necessary procedure for the diagnostic evaluation of suspected peripheral arterial disease. It is unsuitable for routine use in the physician's office.

Recently, however, a number of other plethysmographic methods have been developed which make use of phenomena such as changes in electric impedance or changes in segmental blood pressure at constant volume to assess regional perfusion. Several of these methods have reached a level of development which makes them clinically valuable.

Medicare coverage is extended to those procedures listed in Category I below when used for the accepted medical indications mentioned above. The procedures in Category II are still considered experimental and are not covered at this time. Denial of claims because a noncovered procedure was used or because there was no medical indication for plethysmographic evaluation of any type should be based on §1862(a)(1) of the Act.

CATEGORY I

Segmental Plethysmography--Included under this procedure are services performed with a regional plethysmograph, differential plethysmograph, recording oscillograph, and a pulse volume recorder.

Electrical Impedance Plethysmography

Ultrasonic Measurement of Blood Flow (Doppler).--While not strictly a plethysmographic method, this is also a useful tool in the evaluation of suspected peripheral vascular disease or preoperative screening of podiatric patients with suspected peripheral vascular compromise. (See §50-7 for the applicable coverage policy on this procedure.)

Oculoplethysmography--See §50-37, Noninvasive Tests of Carotid Function.

Strain Gauge Plethysmography--This test is based on recording the non-pulsatile aspects of inflowing blood at various points on an extremity by a mercury-in-silastic strain gauge sensor. The instrument consists of a chart recorder, an automatic cuff inflation and deflation system, and a recording manometer.

CATEGORY II

The following methods have not yet reached a level of development such as to allow their routine use in the evaluation of suspected peripheral vascular disease.

Inductance Plethysmography--This method is considered experimental and does not provide reproducible results.

Capacitance Plethysmography--This method is considered experimental and does not provide reproducible results.

Mechanical Oscillometry--This is a non-standardized method which offers poor sensitivity and is not considered superior to the simple measurement of peripheral blood pressure.

Photoelectric Plethysmography--This method is considered useful only in determining whether or not a pulse is present and does not provide reproducible measurements of blood flow.

Differential plethysmography, on the other hand, is a system which uses an impedance technique to compare pulse pressures at various points along a limb, with a reference pressure at the mid-brachial or wrist level. It is not clear whether this technique, as usually performed in the physician's office, meets the definition of plethysmography because quantitative measurements of blood flow are usually not made. It has been concluded, in any event, that the differential plethysmography system is a blood pulse recorder of undetermined value, which has the potential for significant overutilization. Therefore, reimbursement for studies done by techniques other than venous occlusive pneumoplethysmography should be denied, at least until additional data on these devices, including controlled clinical studies, become available.

50-7 ULTRASOUND DIAGNOSTIC PROCEDURES

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

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

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

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

Echoencephalography, (Diencephalic Midline) (A-Mode)

Echoencephalography, Complete (Diencephalic Midline and Ventricular Size)

Ocular and Orbital Echography (A-Mode)

Covered procedures include efforts to determine the suitability of aphakic patients for implantation of an artificial lens (pseudophakoi) following cataract surgery.

Ocular and Orbital Sonography (B-Mode)

Echocardiography, Pericardial Effusion (M-Mode)

Pericardiocentesis, by Ultrasonic Guidance

Echocardiography, Cardiac Valve(s) (M-Mode)

Echocardiography, Complete (M-Mode)

Echocardiography, limited (e.g., follow-up or limited study) (M-Mode)

Pleural Effusion Echography

Thoracentesis, by Ultrasonic Guidance

Abdominal Sonography, complete survey study (B-Scan)

Abdominal Sonography, limited (e.g., follow-up or limited study) (B-Scan)

Abdominal sonography is not synonymous with ultrasound examination of individual organs.

Renal Cyst Aspiration, by Ultrasonic Guidance

Renal Biopsy, by Ultrasonic Guidance

Pancreas Sonography (B-Scan)

Pancreatic sonography has proven effective in diagnosing pseudocysts.

Spleen Sonography (B-Scan)

Abdominal Aorta Echography (A-Mode)

Abdominal Aorta Sonography (B-Scan)

Retroperitoneal Sonography (B-Scan)

Retroperitoneal sonography does not include planning of fields for radiation therapy.

Urinary Bladder Sonography (B-Scan)

Urinary bladder sonography does not include staging of bladder tumors.

Pregnancy Diagnosis sonography (B-Scan)

Fetal Age Determination (Biparietal Diameter) Sonography (B-Scan)

Fetal Growth Rate Sonography (B-Scan)

Placenta Localization Sonography (B-Scan)

Pregnancy Sonography, Complete (B-Scan)

Molar Pregnancy Diagnosis Sonography (B-Scan)

Ectopic Pregnancy Diagnosis sonography (B-Scan)

Passive Testing (Antepartum Monitoring of Fetal Heart Rate In the Resting Fetus)

Intrauterine Contraceptive Device Sonography (B-Scan)

Pelvic Mass Diagnosis Sonography (B-Scan)

Amniocentesis, by Ultrasonic Guidance

Arterial Flow Study, Peripheral (Doppler)

Venous Flow Study, Peripheral (Doppler)

Arterial Aneurysm, Peripheral (B-Scan)

Radiation Therapy Planning Sonography (B-Scan)

Thyroid Echography (A-Mode)

Thyroid Sonography (B-Scan)

Breast Echography (A-Mode)

Breast Sonography (B-Scan)

Hepatic Sonography (B-Scan)

Gallbladder Sonography

Renal Sonography

| **Two-Dimensional Echocardiography (B-Mode)**

CATEGORY II (Clinical reliability and efficacy not proven).

B-Scan for atherosclerotic narrowing of peripheral arteries.

Monitoring of cardiac output (Doppler)

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

Cross refer: §50-37.

50-8 CONSULTATION SERVICES RENDERED BY A PODIATRIST IN A SKILLED NURSING FACILITY

Consultation services rendered by a podiatrist in a skilled nursing facility are covered if the services are reasonable and necessary and do not come within any of the specific statutory exclusions. Section 1862(a)(13) of the Act excludes payment for the treatment of flat foot conditions, the treatment of subluxations of the foot, and routine foot care. To determine whether the consultation comes within the foot care exclusions, apply the same rule as for initial diagnostic examinations, i.e., where services are performed in connection with specific symptoms or complaints which suggest the need for covered services, the services are covered regardless of the resulting diagnosis. The exclusion of routine physician examinations is also pertinent and would generally exclude podiatric consultation performed on all patients in a skilled nursing facility on a routine basis for screening purposes, except in those cases where a specific foot ailment is involved. Section 1862(a)(7) of the Act excludes payment for routine physical checkups.

Cross-refer: Intermediary Manual, §§3157, 3158; Carriers Manual, §2323

50-8.1 SERVICES PROVIDED FOR THE DIAGNOSIS AND TREATMENT OF DIABETIC SENSORY NEUROPATHY WITH LOSS OF PROTECTIVE SENSATION (AKA DIABETIC PERIPHERAL NEUROPATHY)

Presently, peripheral neuropathy, or diabetic sensory neuropathy, is the most common factor leading to amputation in people with diabetes. In diabetes, sensory neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Diabetic sensory neuropathy with LOPS is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule [see 42 C.F.R. § 411.15 (l)(1)(i)]. Foot exams for people with diabetic sensory neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every six months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.

A. The examination includes:

- 1) a patient history, and
- 2) a physical examination that must consist of *at least* the following elements:
 - a. visual inspection of forefoot and hindfoot (including toe web spaces);
 - b. evaluation of protective sensation;
 - c. evaluation of foot structure and biomechanics;
 - d. evaluation of vascular status and skin integrity;
 - e. evaluation of the need for special footwear; and
- 3) patient education.

A. Treatment includes, but is not limited to:

- 1) local care of superficial wounds;
- 2) debridement of corns and calluses; and
- 3) trimming and debridement of nails.

The diagnosis of diabetic sensory neuropathy with LOPS should be established and documented prior to coverage of foot care. Other causes of peripheral neuropathy should be considered and investigated by the primary care physician prior to initiating or referring for foot care for persons with LOPS.

50-9 GASTROPHOTOGRAPHY

Gastrophotography is an accepted procedure for diagnosis and treatment of gastrointestinal disorders. The photographic record provided by this procedure is often necessary for consultation and/or followup 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 reoperation. Therefore, program reimbursement may be made for this procedure.

50-10 VABRA ASPIRATOR

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

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

Cross-refer: Intermediary Manual, §3157; Carriers Manual §2320; §50-4

50-12 COMPUTERIZED TOMOGRAPHY

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

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

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

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

Continue to review claims for CT scans for evidence of abuse which might include the absence of reasonable indications for the scans, an excessive number of scans or unnecessarily expensive types of scans considering the facts in the particular cases.

C. Approved Models of CT Equipment.--

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

- o The model must be known to the Food and Drug Administration, and
- o Must be in the full market release phase of development.

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

2. Evidence of Approval

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

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

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

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

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

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

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

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

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

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

E. Multiplanar Diagnostic Imaging (MPDI).--(Effective for services performed on or after 6-11-85.)

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

50-13 MAGNETIC RESONANCE IMAGING (Effective for services performed on or after 11-22-85.)

Magnetic resonance imaging (MRI), formerly called nuclear magnetic resonance (NMR), is covered under Medicare when furnished as described below for the types of covered conditions described in this instruction.

A. General

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

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

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

B. Covered Clinical Applications--Although several uses of MRI are still considered investigational and some uses are clearly contraindicated (see subsection D), MRI is considered medically efficacious for a number of uses. Use the following descriptions as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific coverages. Coverage is limited to MRI units which have received FDA premarket approval, and such units must be operated within the parameters specified by the approval. As with all items and services, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

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

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

Effective for services provided on or after March 22, 1994, MRI may also be covered to diagnose disc disease without regard to whether radiological imaging has been tried first to diagnose the problem.

C. Gating Devices and Surface Coils (Effective for Services On or After March 4, 1991)--Gating devices which eliminate distorted images caused by cardiac and respiratory movement cycles are now considered state of the art techniques and may be covered. Surface and other specialty coils may also be covered, as they are used routinely for high resolution imaging where small limited regions of the body are studied. They produce high signal-to-noise ratios resulting in images of enhanced anatomic detail.

D. Contraindications and Noncovered Uses--

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

2. Noncovered Uses.--Several uses of MRI have been identified as investigational and are not covered. These include measurement of blood flow and spectroscopy. In addition, MRI is not suitable for the imaging of cortical bone and calcifications and for procedures involving spatial resolution of bone or calcifications.

50-14 MAGNETIC RESONANCE ANGIOGRAPHY

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

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

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

In a National Coverage Analysis decision memorandum (#CAG-00142N), issued on April 15, 2003, CMS reviewed scientific and clinical literature on MRA, and set forth its basis for the following coverage policy. Below are the only indications for which Medicare coverage is allowed for MRA. All other uses of MRA not listed in this manual are not covered.

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

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

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

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

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

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

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

C. Abdomen and Pelvis.--Effective for dates of service on or after July 1, 1999, MRA is covered for pre-operative evaluation of patients undergoing elective abdominal aortic aneurysm (AAA) repair. Scientific evidence reveals MRA is considered comparable to CA in determining the extent of AAA, as well as evaluating aortoiliac occlusion disease and renal artery pathology that may be necessary in the surgical planning of AAA repair. These studies also reveal that MRA could provide a net benefit to the patient. If preoperative CA is avoided, then patients are not exposed to the risks associated with invasive procedures, contrast media, end-organ damage, or arterial injury.

Effective for dates of service on or after July 1, 2003, MRA coverage has been expanded to include imaging the renal arteries and the aortoiliac arteries in the absence of AAA or aortic dissection. MRA should be obtained in those circumstances in which using MRA is expected to avoid obtaining CA, when physician history, physical examination, and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. However, CA may be ordered after obtaining the results of an MRA in those rare instances where medical necessity is demonstrated.

D. Chest.--

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

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

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

50-15 ELECTROCARDIOGRAPHIC SERVICES

Reimbursement may be made under Part B for electrocardiographic (EKG) services rendered by a physician or incident to his/her services or by an approved laboratory or an approved supplier of portable X-ray services. Since there is no coverage for EKG services of any type rendered on a screening basis or as part of a routine examination, the claim must indicate the signs and symptoms or other clinical reason necessitating the services.

A separate charge by an attending or consulting physician for EKG interpretation is allowed only when it is the normal practice to make such charge in addition to the regular office visit charge. No payment is made for EKG interpretations by individuals other than physicians.

On a claim involving EKG services furnished by a laboratory or a portable X-ray supplier, identify the physician ordering the service and, when the charge includes both the taking of the tracing and its interpretation, include the identity of the physician making the interpretation. No separate bill for the services of a physician is paid unless it is clear that he/she was the patient's attending physician or was acting as a consulting physician. The taking of an EKG in an emergency, i.e., when the patient is or may be experiencing what is commonly referred to as a heart attack, is covered as a laboratory service or a diagnostic service by a portable X-ray supplier only when the evidence shows that a physician was in attendance at the time the service was performed or immediately thereafter.

Where EKG services are rendered in the patient's home and the laboratory's or portable X-ray supplier's charge is higher than that imposed for the same service when performed in the laboratory or portable X-ray supplier's office, the medical need for home service should be documented. In the absence of such justification, reimbursement for the service if otherwise medically necessary should be based on the reasonable charge applicable when performed in the laboratory or X-ray supplier's office.

The documentation required in the various situations mentioned above must be furnished not only when the laboratory or portable X-ray supplier bills the patient or carrier for its service, but also when such a facility bills the attending physician who, in turn, bills the patient or carrier for the EKG services. (In addition to the evidence required to document the claim, the laboratory or portable X-ray supplier must maintain in its records the referring physician's written order and the identity of the employee taking the tracing.)

Long Term EKG Monitoring, also referred to as long-term EKG recording, Holter recording, or dynamic electrocardiography, is a diagnostic procedure which provides a continuous record of the electrocardiographic activity of a patient's heart while he is engaged in his daily activities.

The basic components of the long-term EKG monitoring systems are a sensing element, the design of which may provide either for the recording of electrocardiographic information on magnetic tape or for detecting significant variations in rate or rhythm as they occur, and a component for either graphically recording the electrocardiographic data or for visual or computer assisted analysis of the information recorded on magnetic tape. The long-term EKG permits the examination in the ambulant or potentially ambulant patient of as many as 70,000 heartbeats in a 12-hour recording while the standard EKG which is obtained in the recumbent position, yields information on only 50 to 60 cardiac cycles and provides only a limited data base on which diagnostic judgments may be made.

Many patients with cardiac arrhythmias are unaware of the presence of an irregularity in heart rhythm. Due to the transient nature of many arrhythmias and the short intervals in which the rhythm of the heart is observed by conventional standard EKG techniques, the offending arrhythmias can go undetected. With the extended examination provided by the long-term EKG, the physician is able not only to detect but also to classify various types of rhythm disturbances and waveform abnormalities and note the frequency of their occurrence. The knowledge of the reaction of the heart to daily activities with respect to rhythm, rate, conduction disturbances, and ischemic changes are of great assistance in directing proper therapy and rehabilitation.

This modality is valuable in both inpatient and outpatient diagnosis and therapy. Long-term monitoring of ambulant or potentially ambulant inpatients provides significant potential for reducing the length of stay for post-coronary infarct patients in the intensive care setting and may result in earlier discharge from the hospital with greater assurance of safety to the patients. The indications for the use of this technique, noted below, are similar for both inpatients and outpatients.

The long-term EKG has proven effective in detecting transient episodes of cardiac dysrhythmia and in permitting the correlation of these episodes with cardiovascular symptomatology. It is also useful for patients who have symptoms of obscure etiology suggestive of cardiac arrhythmia. Examples of such symptoms include palpitations, chest pain, dizziness, light-headedness, near syncope, syncope, transient ischemic episodes, dyspnea, and shortness of breath.

This technique would also be appropriate at the time of institution of any arrhythmic drug therapy and may be performed during the course of therapy to evaluate response. It is also appropriate for evaluating a change of dosage and may be indicated shortly before and after the discontinuation of anti-arrhythmic medication. The therapeutic response to a drug whose duration of action and peak of effectiveness is defined in hours cannot be properly assessed by examining 30-40 cycles on a standard EKG rhythm strip. The knowledge that all patients placed on anti-arrhythmic medication do not respond to therapy and the known toxicity of anti-arrhythmic agents clearly indicate that proper assessment should be made on an individual basis to determine whether medication should be continued and at what dosage level.

The long-term EKG is also valuable in the assessment of patients with coronary artery disease. It enables the documentation of etiology of such symptoms as chest pain and shortness of breath. Since the standard EKG is often normal during the intervals between the episodes of precordial pain, it is essential to obtain EKG information while the symptoms are occurring. The long-term EKG has enabled the correlation of chest symptoms with the objective evidence of ST-segment abnormalities.

It is appropriate for patients who are recovering from an acute myocardial infarction or coronary insufficiency before and after discharge from the hospital, since it is impossible to predict which of these patients is subject to ventricular arrhythmias on the basis of the presence or absence of rhythm disturbances during the period of initial coronary care. The long-term EKG enables the physician to identify patients who are at a higher risk of dying suddenly in the period following an acute myocardial infarction. It may also be reasonable and necessary where the high-risk patient with known cardiovascular disease advances to a substantially higher level of activity which might trigger increased or new types of arrhythmias necessitating treatment. Such a high-risk case would be one in which there is documentation that acute phase arrhythmias have not totally disappeared during the period of convalescence.

In view of recent developments in cardiac pacemaker monitoring techniques (see CIA 50-1), the use of the long-term EKG for routine assessment of pacemaker function can no longer be justified. Its use for the patient with an internal pacemaker would be covered only when he has symptoms suggestive of arrhythmia not revealed by the standard EKG or rhythm strip.

These guidelines are intended as a general outline of the circumstances under which the use of this diagnostic procedure would be warranted. Each patient receiving a long-term EKG should be evaluated completely, prior to performance of this diagnostic study. A complete history and physical examination should be obtained and the indications for use of the long-term EKG should be reviewed by the referring physician.

The performance of a long-term EKG does not necessarily require the prior performance of a standard EKG. Nor does the demonstration of a normal standard EKG preclude the need for a long-term EKG. Finally, the demonstration of an abnormal standard EKG does not obviate the need for a long-term EKG if there is suspicion that the dysrhythmia is transient in nature.

A period of recording of up to 24 hours would normally be adequate to detect most transient arrhythmias and provide essential diagnostic information. The medical necessity for longer periods of monitoring must be documented.

Medical documentation for adjudicating claims for the use of the long-term EKG should be similar to other EKG services, X-ray services, and laboratory procedures. Generally, a statement of the diagnostic impression of the referring physician with an indication of the patient's relevant signs and symptoms should be sufficient for purposes of making a determination regarding the reasonableness and medical necessity for the use of this procedure. However, the intermediaries or carriers should require whatever additional documentation their medical consultants deem necessary to properly adjudicate the individual claim where the information submitted is not adequate.

It should be noted that the recording device furnished to the patient is simply one component of the diagnostic system and a separate charge for it will not be recognized under the durable medical equipment benefit.

Patient-Activated EKG Recorders, distributed under a variety of brand names, permit the patient to record an EKG upon manifestation of symptoms, or in response to a physician's order (e.g., immediately following strong exertion). Most such devices also permit the patient to simultaneously voice-record in order to describe symptoms and/or activity. In addition, some of these devices permit transtelephonic transmission of the recording to a physician's office, clinic, hospital, etc., having a decoder/recorder for review and analysis, thus eliminating the need to physically transport the tape. Some of these devices also permit a "time sampling" mode of operation. However, the "time sampling" mode is not covered--only the patient-activated mode of operation, when used for the indications described below, is covered at this time.

Services in connection with patient-activated EKG recorders are covered when used as an alternative to the long-term EKG monitoring (described above) for similar indications--detecting and characterizing symptomatic arrhythmias, regulation of anti-arrhythmic drug therapy, etc. Like long-term EKG monitoring, use of these devices is covered for evaluating patients with symptoms of obscure etiology suggestive of cardiac arrhythmia such as palpitations, chest pain, dizziness, lightheadedness, near syncope, syncope, transient ischemic episodes, dyspnea and shortness of breath.

As with long-term EKG monitors, patient-activated EKG recorders may be useful for both inpatient and outpatient diagnosis and therapy. While useful for assessing some post-coronary infarct patients in the hospital setting, these devices should not, however, be covered for outpatient monitoring of recently discharged post-infarct patients.

Computer Analyzed Electrocardiograms.--Computer interpretation of EKG's is recognized as a valid and effective technique which will improve the quality and availability of cardiology services. Reimbursement may be made for such computer service when furnished in the setting and under the circumstances required for coverage of other electrocardiographic services. Where either a laboratory's or a portable x-ray supplier's charge for EKG services includes the physician review and certification of the printout as well as the computer interpretation, the certifying physician must be identified on the HCFA-1490 before the entire charge can be considered a reimbursable charge. Where the laboratory's (or portable x-ray supplier's) reviewing physician is not identified, the carrier should conclude that no professional component is involved and make its charge determination accordingly. If the supplying laboratory (or portable x-ray supplier when supplied by such a facility) does not include professional review and certification of the hard copy, a charge by the patient's physician may be recognized for the service. In any case the charge for the physician component should be substantially less than that for physician interpretation of the conventional EKG tracing in view of markedly reduced demand on the physician's time where computer interpretation is involved. Considering the unit cost reduction expected of this innovation, the total charge for the complete EKG service (taking of tracing and interpretation) when computer interpretation is employed should never exceed that considered reasonable for the service when physician interpretation is involved.

Transtelephonic Electrocardiographic Transmissions (Formerly Referred to as EKG Telephone Reporter Systems).--Effective for services furnished on and after March 1, 1980, coverage is extended to include the use of transtelephonic electrocardiographic (EKG) transmissions as a diagnostic service for the indications described below, when performed with equipment meeting the standards described below, subject to the limitations and conditions specified below. Coverage is further limited to the amounts payable with respect to the physician's service in interpreting the results of such transmissions, including charges for rental of the equipment. The device used by the beneficiary is part of a total diagnostic system and is not considered durable medical equipment.

1. Covered Uses.--The use of transtelephonic EKGs is covered for the following uses:
 - a. To detect, characterize, and document symptomatic transient arrhythmias;
 - b. To overcome problems in regulating antiarrhythmic drug dosage;
 - c. To carry out early posthospital monitoring of patients discharged after myocardial infarction; (only if 24-hour coverage is provided, see 4. below).

Since cardiology is a rapidly changing field, some uses other than those specified above may be covered if, in the judgment of the contractor's medical consultants, such a use was justifiable in the particular case. The enumerated uses above represent uses for which a firm coverage determination has been made, and for which contractors may make payment without extensive claims development or review.

2. Specifications for Devices.--The devices used by the patient are highly portable (usually pocket-sized) and detect and convert the normal EKG signal so that it can be transmitted via ordinary telephone apparatus to a receiving station. At the receiving end, the signal is decoded and transcribed into a conventional EKG. There are numerous devices available which transmit EKG readings in this fashion. For purposes of Medicare coverage, however, the transmitting devices must meet at least the following criteria:

- a. They must be capable of transmitting EKG Leads, I, II, or III;
- b. These lead transmissions must be sufficiently comparable to readings obtained by a conventional EKG to permit proper interpretation of abnormal cardiac rhythms.

3. Potential for Abuse - Need for Screening Guidelines.--While the use of these devices may often compare favorably with more costly alternatives, this is the case only where the information they contribute is actively utilized by a knowledgeable practitioner as part of overall medical management of the patient. Consequently, it is vital that contractors be aware of the potential for abuse of these devices, and adopt necessary screening and physician education policies to detect and halt potentially abusive situations. For example, use of these devices to diagnose and treat suspected arrhythmias as a routine substitute for more conventional methods of diagnosis, such as a careful history, physical examination, and standard EKG and rhythm strip would not be appropriate. Moreover, contractors should require written justification for use of such devices in excess of 30 consecutive days in cases involving detection of transient arrhythmias.

Contractors may find it useful to review claims for these devices with a view toward detecting patterns of practice which may be useful in developing schedules which may be adopted for screening such claims in the future.

4. Twenty-four Hour Coverage.--No payment may be made for the use of these devices to carry out early posthospital monitoring of patients discharged after myocardial infarction unless provision is made for 24 hour coverage in the manner described below.

Twenty-four hour coverage means that there must be, at the monitoring site (or sites) an experienced EKG technician receiving calls; tape recording devices do not meet this requirement. Further, such technicians should have immediate access to a physician, and have been instructed in when and how to contact available facilities to assist the patient in case of emergencies.

Cross-refer: HCFA-Pub. 13-3, §§3101.5, 3110, 3112.3, HCFA-Pub.14-3, §§2070, 2255, 2050.1

50-16 HEMORHEOGRAPH

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

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

NOTE: This instrument is not a plethysmograph and is not considered as such. A plethysmograph measures and records changes in the size of a body part as modified by the circulation of blood in that part. The hemorheograph, on the other hand, measures surface blood flow in the skin; it does not measure total blood flow in a digit or limb. (See §50-6.)

50-17 LABORATORY TESTS - CRD PATIENTS

A. Laboratory tests are essential to monitor the progress of CRD patients. The following list and frequencies of tests constitute the level and types of routine laboratory tests that are covered. Bills for other types of tests are considered nonroutine. Routine tests at greater frequencies must include medical justification. Nonroutine tests generally are justified by the diagnosis. The routinely covered regimen includes the following tests:

Per Dialysis

All hematocrit or hemoglobin and clotting time tests furnished incident to dialysis treatments.

Per Week

Prothrombin time for patients on anticoagulant therapy

Serum Creatinine

Per Week or Thirteen Per Quarter

BUN

Monthly

CBC	Serum Calcium
Serum Potassium	Serum Chloride
Serum Bicarbonate	Serum Phosphorous
Total Protein	Serum Albumin
Alkaline Phospatase	AST, SGOT
LDH	

Guidelines for tests other than those routinely performed include:

Serum Aluminum - one every 3 months

Serum Ferritin - one every 3 months

The following tests for hepatitis B are covered when patients first enter a dialysis facility: hepatitis B surface antigen (HBsAg) and Anti-HBs. Coverage of future testing in these patients depends on their serologic status and on whether they have been successfully immunized against hepatitis B virus. The following table summarizes the frequency of serologic surveillance for hepatitis B. Tests furnished according to this table do not require additional documentation and are paid separately because payment for maintenance dialysis treatments does not take them into account.

<u>Vaccination and Serologic Status</u>	<u>Frequency of Screening</u>	
	<u>HBsAg Patients</u>	<u>Anti-HBs Patients</u>
UNVACCINATED		
Susceptible	Monthly	Semiannually
HBsAg Carrier	Annually	None
Anti-HBs-Positive (1)	None	Annually
VACCINATED		
Anti-HBs-Positive (1)	None	Annually
Low Level or No Anti-HBs	Monthly	Semiannually

(1) At least 10 sample ration units by radioimmunoassay or positive by enzyme immunoassay.

Patients who are in the process of receiving hepatitis B vaccines, but have not received the complete series, should continue to be routinely screened as susceptible. Between one and six months after the third dose, all vaccines should be tested for anti-HBs to confirm their response to the vaccine. Patients who have a level of anti-HBs of at least 10 sample ratio units (SRUs) by radioimmunoassay (RIA) or who are positive by enzyme immunoassay (EIA) are considered adequate responders to vaccine and need only be tested for anti-HBs annually to verify their immune status. If anti-HBs drops below 10 SRUs by RIA or is negative by EIA, a booster dose of hepatitis B vaccine should be given.

B. Laboratory tests are subject to the normal coverage requirements. If the laboratory services are performed by a free-standing facility, be sure it meets the conditions of coverage for independent laboratories.

50-18 ELECTRON MICROSCOPE

The electron microscope has been used in the examination of biopsies for years; its efficacy, and therefore its Medicare coverage, is not being questioned. However, there are less expensive methods for examining biopsies which are normally adequate. The additional expense for the electron microscope is normally warranted only when distinguishing different types of nephritis from renal needle biopsies or when there is an uncertain diagnosis from the pathologist. When an uncertain diagnosis from the pathologists results from a less expensive method of examination and an electron microscope examination is therefore necessary, both biopsy examinations are covered. Where the additional expense for an electron microscope examination is not warranted, payment is based upon the less costly methods of examining biopsies.

50-19 PRONOUNCEMENT OF DEATH

According to established legal principles, an individual is not considered deceased until there has been official pronouncement of death. An individual is therefore considered to have expired as of the time he/she is pronounced dead by a person who is legally authorized to make such a pronouncement, usually a physician. Reasonable and necessary medical services rendered up to and including pronouncement of death by a physician are covered diagnostic or therapeutic services.

50-20 DIAGNOSTIC PAP SMEARS

(Effective for services performed on and after May 15, 1978)

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

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

In respect to the last bullet, the contractor's medical staff must determine whether in a particular case a previous malignancy at another site is an indication for a diagnostic pap smear or whether the test must be considered a screening pap smear as described in §50-20.1.

Use the following CPT codes for indicating diagnostic pap smears:

- o 88150 Cytopathology, smears, cervical or vaginal (e.g., Papanicolaou), up to three smears; screening by technician under physician supervision; or
- o 88151 Cytopathology, smears, cervical or vaginal (e.g., Papanicolaou), up to three smears; requiring interpretation by physician.

50-20.1 SCREENING PAP SMEARS AND PELVIC EXAMINATIONS FOR EARLY DETECTION OF CERVICAL OR VAGINAL CANCER

(For screening pap smears, effective for services performed on or after July 1, 1990. For pelvic examinations including clinical breast examination, effective for services furnished on or after January 1, 1998.)

A screening pap smear (use HCPCS code P3000 Screening Papanicolaou smear, cervical or vaginal, up to three smears; by technician under physician supervision or P3001 Screening Papanicolaou smear, cervical or vaginal, up to three smears requiring interpretation by physician). (Use HCPCS codes G0123 Screening Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, screening by cytotechnologist under physician supervision or G0124 Screening Cytopathology, cervical or vaginal (any reporting system) collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician) and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and

pelvic examination (including clinical breast examination) (use HCPCS code G0101 cervical or vaginal cancer screening; pelvic and clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- o She has not had such a test during the preceding 3 years or is a woman of childbearing age (§1861(nn) of the Act).
- o There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every 3 years.

High risk factors for cervical and vaginal cancer are:

- o Early onset of sexual activity (under 16 years of age)
- o Multiple sexual partners (five or more in a lifetime)
- o History of sexually transmitted disease (including HIV infection)
- o Fewer than three negative or any pap smears within the previous 7 years; and
- o DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

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

- o *V76.2, special screening for malignant neoplasms of the cervix, indicates low risk; and*
- o *V15.89, other specified personal history presenting hazards to health, indicates high risk.*

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

Definitions:

A woman as described in §1861(nn) of the Act is a woman who is of childbearing age and has had a pap smear test during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality, or is at high risk of developing cervical or vaginal cancer.

A woman of childbearing age is one who is premenopausal and has been determined by a physician or other qualified practitioner to be of childbearing age, based upon the medical history or other findings.

Other qualified practitioner“, as defined in 42 CFR 410.56(a) includes a certified nurse midwife (as defined in §1861(gg) of the Act), or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861(aa) of the Act) who is authorized under State law to perform the examination.

Screening Pelvic Examination:

Section 4102 of the Balanced Budget Act of 1997 provides for coverage of screening pelvic examinations (including a clinical breast examination) for all female beneficiaries, effective January 1, 1998, subject to certain frequency and other limitations. A screening pelvic examination (including a clinical breast examination) should include at least seven of the following eleven elements:

- o Inspection and palpation of breasts for masses or lumps, tenderness, symmetry, or nipple discharge.
- o Digital rectal examination including sphincter tone, presence of hemorrhoids, and rectal masses. Pelvic examination (with or without specimen collection for smears and cultures) including:
 - o External genitalia (for example, general appearance, hair distribution, or lesions).
 - o Urethral maetus (for example, size, location, lesions, or prolapse).
 - o Urethra (for example, masses, tenderness, or scarring).
 - o Bladder (for example, fullness, masses, or tenderness).
 - o Vagina (for example, general appearance, estrogen effect, discharge lesions, pelvic support, cystocele, or rectocele).
 - o Cervix (for example, general appearance, lesions, or discharge).
 - o Uterus (for example, size, contour, position, mobility, tenderness, consistency, descent, or support).
 - o Adnexa/parametria (for example, masses, tenderness, organomegaly, or nodularity).
 - o Anus and perineum.

This description is from *Documentation Guidelines for Evaluation and Management Services*, published in May 1997 and was developed by the Health Care Financing Administration and the American Medical Association.

50-21 MAMMOGRAMS

(Effective for mammograms performed on or after May 15, 1978.)

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

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

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

Cross-refer: Carriers Manual, §2070, Intermediary Manual, §3101.5.

50-22 CHALLENGE INGESTION FOOD TESTING

(Effective for services performed on and after August 1, 1978.)

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 section 1862(a)(1) of the Medicare law, and no program payment is made for this procedure when it is so used.

50-23 HISTOCOMPATIBILITY TESTING

(Effective for services performed on and after August 1, 1978.)

Histocompatibility testing involves the matching or typing of the human leucocyte antigen (HLA). This testing is safe and effective when it is performed on patients:

- A. In preparation for a kidney transplant;
- B. In preparation for bone marrow transplantation;
- C. In preparation for blood platelet transfusions (particularly where multiple infusions are involved); or
- D. Who are suspected of having ankylosing spondylitis.

This testing is covered under Medicare when used for any of the indications listed in A, B, and C and if it is reasonable and necessary for the patient.

It is covered for ankylosing spondylitis in cases where other methods of diagnosis would not be appropriate or have yielded inconclusive results. Request documentation supporting the medical necessity of the test from the physician in all cases where ankylosing spondylitis is indicated as the reason for the test.

50-24 HAIR ANALYSIS--NOT COVERED

Hair analysis to detect mineral traces as an aid in diagnosing human disease is not a covered service under Medicare.

The correlation of hair analysis to the chemical state of the whole body is not possible at this time, and therefore this diagnostic procedure cannot be considered to be reasonable and necessary under §1862(a)(1) of the law.

50-25 ESOPHAGEAL MANOMETRY

(Effective for services performed on and after October 2, 1978).

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.

50-26 DENTAL EXAMINATION PRIOR TO KIDNEY TRANSPLANTATION

Despite the "dental services exclusion" in §1862(a)(12) of the Act (see Intermediary Manual, §3162; Carriers Manual, §2336), an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery is a covered service. This is because the purpose of the examination is not for the care of the teeth or structures directly supporting the teeth. Rather, the examination is for the identification, prior to a complex surgical procedure, of existing medical problems where the increased possibility of infection would not only reduce the chances for successful surgery but would also expose the patient to additional risks in undergoing such surgery.

Such a dental or oral examination would be covered under Part A of the program if performed by a dentist on the hospital's staff, or under Part B if performed by a physician. (When performing a dental or oral examination, a dentist is not recognized as a physician under §1861(r) of the law.) (See Carriers Manual §2020.3.)

50-27 XENON SCAN

(Effective for services performed on and after September 1, 1979).

Program payment may be made for this diagnostic procedure which involves perfusion lung imaging with 133 xenon. However, review for evidence of abuse which might include absence of reasonable indications, inappropriate sequence, or excessive number or kinds of procedures used in the care of individual patients.

50-28 HOSPITAL AND SKILLED NURSING FACILITY ADMISSION DIAGNOSTIC PROCEDURES

These instructions clarify the application of the reasonable and necessary payment exclusion to diagnostic procedures, such as chest X-rays, urinalysis, etc. provided to patients upon admission to a hospital or skilled nursing facility.

The major factors which support a determination that a diagnostic procedure performed as part of the admitting procedure to a hospital or skilled nursing facility is reasonable and necessary are:

A. The test is specifically ordered by the admitting physician (or a hospital or skilled nursing facility staff physician having responsibility for the patient where there is no admitting physician): i.e., it is not furnished under the standing orders of a physician for his patients;

B. The test is medically necessary for the diagnosis or treatment of the individual patient's condition; and

C. The test does not unnecessarily duplicate the same test performed on an outpatient basis prior to admission or performed in connection with a recent hospital or skilled nursing facility admission.

Where you have not already done so, consult with PROs to obtain information gathered by the PROs on a sample basis as to whether X-rays and diagnostic tests are being specifically ordered as described under subsection (A).

50-29 CYTOGENETIC STUDIES

The term cytogenetic studies is used to describe the microscopic examination of the physical appearance of human chromosomes. Medicare covers these tests when they are reasonable and necessary for the diagnosis or treatment of **the following conditions**:

(Effective for services performed on and after October 1, 1979)

- o Genetic disorders (e.g., mongolism) in a fetus (See Intermediary Manual, §3101.13);
- o Failure of sexual development; or
- o Chronic myelogenous leukemia.

(Effective for services performed on or after **July 16, 1998**)

- o Acute leukemias lymphoid (FAB L1-L3), myeloid (FAB M0-M7), and unclassified; or
- o Myelodysplasia.

50-30 NUCLEAR RADIOLOGY PROCEDURE

(Effective for services performed on and after September 1, 1979)

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

50-31 EVOKESED RESPONSE TESTS

(Effective for services furnished on and after January 15, 1980)

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.

50-32 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA)

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon.

PTA is covered to treat the following indications:

o Atherosclerotic obstructive lesions:

- In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.

- Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:

- + Angina refractory to optimal medical management;
- + Objective evidence of myocardial ischemia; and
- + Lesions amenable to angioplasty;

- Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.

o Obstructive lesions of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

PTA is not covered to treat obstructive lesions of the carotid artery except in the following circumstance:

o Effective July 1, 2001, Medicare will cover PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration (FDA) approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service only when provided in the context of such a clinical trial, and therefore is considered a covered service for the purposes of these trials. Performance of PTA in the carotid artery when used to treat obstructive lesions outside of approved protocols governing Category B IDE clinical trials remains a noncovered service.

PTA is not covered to treat obstructive lesions of the vertebral and cerebral arteries. The safety and efficacy of these procedures have not been established.

50-33 UROFLOWMETRIC EVALUATIONS (Effective for services performed on and after January 1, 1980)

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

50-34 OBSOLETE OR UNRELIABLE DIAGNOSTIC TESTS

A. Diagnostic Tests (Effective for services performed on or after May 15, 1980).--Do not routinely pay for the following diagnostic tests because they are obsolete and have been replaced by more advanced procedures. The listed tests may be paid for only if the medical need for the procedure is satisfactorily justified by the physician who performs it. When the services are subject to PRO review, the PRO is responsible for determining that satisfactory medical justification exists. When the services are not subject to PRO review, the intermediary or carrier is responsible for determining that satisfactory medical justification exists. This includes:

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

B. Cardiovascular Tests (Effective for services performed on or after January 1, 1997).--Do not pay for the following phonocardiography and vectorcardiography diagnostic tests because they have been determined to be outmoded and of little clinical value. They include:

- o CPT code 93201, Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician),

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

50-35 SWEAT TEST

The sweat test is an important diagnostic tool in cystic fibrosis and may be covered when used for that purpose. Usage of the sweat test as a predictor of efficacy of sympathectomy in peripheral vascular disease is unproven and, therefore, is not covered.

50-36 POSITRON EMISSION TOMOGRAPHY (PET) SCANS

I. General Description

Positron emission tomography (PET) is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the [human] body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-[F-18] Fluoro-D-Glucose (FDG), that are administered intravenously to the patient.

The following indications may be covered for PET under certain circumstances. Details of Medicare PET coverage are discussed later in this section. Unless otherwise indicated, the clinical conditions below are covered when PET utilizes FDG as a tracer.

NOTE: This manual section lists all Medicare-covered uses of PET scans. A particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

Clinical Condition	Effective Date	Coverage
Solitary Pulmonary Nodules (SPNs)	January 1, 1998	Characterization
Lung Cancer (Non Small Cell)	January 1, 1998	Initial staging
Lung Cancer (Non Small Cell)	July 1, 2001	Diagnosis, staging and restaging
Esophageal Cancer	July 1, 2001	Diagnosis, staging and restaging
Colorectal Cancer	July 1, 1999	Determining location of tumors if rising CEA level suggests recurrence
Colorectal Cancer	July 1, 2001	Diagnosis, staging and restaging
Lymphoma	July 1, 1999	Staging and restaging only when used as an alternative to Gallium scan
Lymphoma	July 1, 2001	Diagnosis, staging and restaging
Melanoma	July 1, 1999	Evaluating recurrence prior to surgery as an alternative to a Gallium scan
Melanoma	July 1, 2001	Diagnosis, staging and restaging; Non-covered for evaluating regional nodes
Breast Cancer	October 1, 2002	As an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; as an adjunct to standard imaging modalities for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated

Head and Neck Cancers (excluding CNS and thyroid)	July 1, 2001	Diagnosis, staging and restaging
Thyroid Cancer	October 1, 2003	Restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and negative I-131 whole body scan performed
Myocardial Viability	July 1, 2001 to September 30, 2002	Covered only following inconclusive SPECT
Myocardial Viability	October 1, 2002	Primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization. SPECT may not be used following an inconclusive PET scan
Refractory Seizures	July 1, 2001	Covered for pre-surgical evaluation only
Perfusion of the heart using Rubidium 82* tracer	March 14, 1995	Covered for noninvasive imaging of the perfusion of the heart
Perfusion of the heart using ammonia N-13* tracer	October 1, 2003	Covered for noninvasive imaging of the perfusion of the heart

*Not FDG-PET.

II. General Conditions of Coverage for FDG PET

A. Allowable FDG PET Systems

1. Definitions: For purposes of this section:

a. "Any FDA approved" means all systems approved or cleared for marketing by the FDA to image radionuclides in the body.

b. "FDA approved" means that the system indicated has been approved or cleared for marketing by the FDA to image radionuclides in the body.

c. "Certain coincidence systems" refers to the systems that have all the following features:

- Crystal at least 5/8-inch thick;
- Techniques to minimize or correct for scatter and/or randoms; and
- Digital detectors and iterative reconstruction.

Scans performed with gamma camera PET systems with crystals thinner than 5/8-inch will not be covered by Medicare. In addition, scans performed with systems with crystals greater than or equal to 5/8-inch in thickness, but that do not meet the other listed design characteristics are not covered by Medicare.

2. Allowable PET systems by covered clinical indication:

Covered Clinical Condition	Allowable Type of FDG PET System		
	Prior to July 1, 2001	July 1, 2001 through December 31, 2001	On or after January 1, 2002
Characterization of single pulmonary nodules	Effective 1/1/1998, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Initial staging of lung cancer (non small cell)	Effective 1/1/1998, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Determining location of colorectal tumors if rising CEA level suggests recurrence	Effective 7/1/1999, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Staging or restaging of lymphoma only when used as an alternative to a gallium scan	Effective 7/1/1999, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Evaluating recurrence of melanoma prior to surgery as an alternative to a gallium scan	Effective 7/1/1999, any FDA approved.	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Diagnosis, staging, and restaging of colorectal cancer	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of esophageal cancer	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of head and neck cancers (excluding CNS and thyroid)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of lung cancer (non small cell)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of lymphoma	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring

Diagnosis, staging, and restaging of melanoma (noncovered for evaluating regional nodes)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Determination of myocardial viability only following an inconclusive SPECT	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Presurgical evaluation of refractory seizures	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Breast Cancer	Not covered	Not covered	Effective October 1, 2002, full and partial ring
Thyroid Cancer	Not covered	Not covered	Effective October 1, 2003, full and partial ring
Myocardial Viability Primary or initial diagnosis prior to revascularization	Not covered	Not covered	Effective October 1, 2002, full and partial ring

B. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions prior to June 30, 2001:

1. Submission of claims for payment must include any information Medicare requires to assure that the PET scans performed were: (a) medically necessary, (b) did not unnecessarily duplicate other covered diagnostic tests, and (c) did not involve investigational drugs or procedures using investigational drugs, as determined by the Food and Drug Administration (FDA).

2. The PET scan entity submitting claims for payment must keep such patient records as Medicare requires on file for each patient for whom a PET scan claim is made.

C. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions as of July 1, 2001:

1. The provider of the PET scan should maintain on file the doctor's referral and documentation that the procedure involved only FDA approved drugs and devices, as is normal business practice.

2. The ordering physician is responsible for documenting the medical necessity of the study and that it meets the conditions specified in the instructions. The physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.

III. Covered Indications for PET Scans and Limitations/Requirements for Usage

For all uses of PET relating to malignancies the following **conditions** apply:

1. Diagnosis: PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific signs and symptoms of disease).

2. Staging and or Restaging: PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

3. Monitoring: Use of PET to monitor tumor response during the planned course of therapy (i.e., when no change in therapy is being contemplated) is not covered except for breast cancer. Restaging only occurs after a course of treatment is completed, and this is covered, subject to the conditions above.

NOTE: In the absence of national frequency limitations, contractors, should, if necessary, develop frequency requirements on any or all of the indications covered on and after July 1, 2001.

IV. Coverage of PET for Perfusion of the Heart

A. Rubidium 82

Effective for services performed on or after March 14, 1995, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) are covered, provided the requirements below are met.

Requirements:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

- For any PET scan for which Medicare payment is claimed for dates of services prior to July 1, 2001, the claimant must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the results of the PET scan. The claimant must also include information on whether the PET scan was done after an inconclusive noninvasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test done prior to the PET scan and whether it was inconclusive or unsatisfactory. These explanations are in the form of special G codes used for billing PET scans using Rb 82. Beginning July 1, 2001, claims should be submitted with the appropriate codes.

B. Ammonia N-13

Effective for services performed on or after October 1, 2003, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical ammonia N-13 are covered, provided the requirements below are met.

Requirements:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

(This NCD last reviewed April 2003.)

V. Coverage of FDG PET for Lung Cancer

The coverage for FDG PET for lung cancer, effective January 1, 1998, has been expanded. Beginning July 1, 2001, usage of FDG PET for lung cancer has been expanded to include diagnosis, staging, and restaging (see section III) of the disease.

A. Effective for services performed on or after January 1, 1998, Medicare covers regional FDG PET chest scans, on any FDA approved scanner, for the characterization of single pulmonary nodules (SPNs). The primary purpose of such characterization should be to determine the likelihood of malignancy in order to plan future management and treatment for the patient.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical file at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

Requirements:

- There must be evidence of primary tumor. Claims for regional PET chest scans for characterizing SPNs should include evidence of the initial detection of a primary lung tumor, usually by computed tomography (CT). This should include, but is not restricted to, a report on the results of such CT or other detection method, indicating an indeterminate or possibly malignant lesion, not exceeding four centimeters (cm) in diameter.

- PET scan claims must include the results of concurrent thoracic CT (as noted above), which is necessary for anatomic information, in order to ensure that the PET scan is properly coordinated with other diagnostic modalities.

- In cases of serial evaluation of SPNs using both CT and regional PET chest scanning, such PET scans will not be covered if repeated within 90 days following a negative PET scan.

NOTE: A tissue sampling procedure (TSP) is not routinely covered in the case of a negative PET scan for characterization of SPNs, since the patient is presumed not to have a malignant lesion, based upon the PET scan results. When there has been a negative PET, the provider must submit additional information with the claim to support the necessity of a TSP, for review by the Medicare contractor.

B. Effective for services performed from January 1, 1998 through June 30, 2001, Medicare approved coverage of FDG PET for initial staging of non-small-cell lung carcinoma (NSCLC).

Limitations: This service is covered only when the primary cancerous lung tumor has been pathologically confirmed; claims for PET must include a statement or other evidence of the detection of such primary lung tumor. The evidence should include, but is not restricted to, a surgical pathology report, which documents the presence of an NSCLC. Whole body PET scan results and results of concurrent computed tomography (CT) and follow-up lymph node biopsy must be properly coordinated with other diagnostic modalities. Claims must include both:

- The results of concurrent thoracic CT, necessary for anatomic information, and
- The results of any lymph node biopsy performed to finalize whether the patient will be a surgical candidate. The ordering physician is responsible for providing this biopsy result to the PET facility.

NOTE: Where the patient is considered a surgical candidate, (given the presumed absence of metastatic NSCLC unless medical review supports a determination of medical necessity of a biopsy) a lymph node biopsy will not be covered in the case of a negative CT and negative PET. A lymph node biopsy will be covered in all other cases, i.e., positive CT + positive PET; negative CT + positive PET; positive CT + negative PET.

C. Beginning July 1, 2001, Medicare covers FDG PET for diagnosis, staging, and restaging of NSCLC. Documentation should be maintained in the beneficiary's medical file to support the medical necessity of the procedure, as is normal business practice.

Requirements: PET is covered in either/or both of the following circumstances:

- **Diagnosis** - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

- **Staging and/or Restaging** - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is

insufficient for the clinical management of the patient and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

VI. Coverage of FDG PET for Esophageal Cancer

A. Beginning July 1, 2001, Medicare covers FDG PET for the diagnosis, staging, and restaging of esophageal cancer. Medical evidence is present to support the use of FDG PET in pre-surgical staging of esophageal cancer.

Requirements: PET is covered in either/or both of the following circumstances:

- Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers as well as in melanoma should be rare.
- Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

VII. Coverage of FDG PET for Colorectal Cancer

Medicare coverage of FDG PET for colorectal cancer where there is a rising level of carcinoembryonic antigen (CEA) was effective July 1, 1999 through June 30, 2001. Beginning July 1, 2001, usage of FDG PET for colorectal cancer has been expanded to include diagnosis, staging, and restaging of the disease (see part III).

A. Effective July 1, 1999, Medicare covers FDG PET for patients with recurrent colorectal carcinomas, which are suggested by rising levels of the biochemical tumor marker CEA.

1. Frequency Limitations: Whole body PET scans for assessment of recurrence of colorectal cancer cannot be ordered more frequently than once every 12 months unless medical necessity documentation supports a separate re-elevation of CEA within this period.

2. Limitations: Because this service is covered only in those cases in which there has been a recurrence of colorectal tumor, claims for PET should include a statement or other evidence of previous colorectal tumor, through June 30, 2001.

B. Beginning July 1, 2001, Medicare coverage has been expanded for colorectal carcinomas for diagnosis, staging and re-staging. New medical evidence supports the use of FDG PET as a useful tool in determining the presence of hepatic/extrahepatic metastases in the primary staging of colorectal carcinoma, prior to selecting a treatment regimen. Use of FDG PET is also supported in evaluating recurrent colorectal cancer beyond the limited presentation of a rising CEA level where the patient presents clinical signs or symptoms of recurrence.

Requirements: PET is covered in either/both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

- Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

VIII. Coverage of FDG PET for Lymphoma

Medicare coverage of FDG PET to stage and re-stage lymphoma as alternative to a Gallium scan, was effective July 1, 1999. Beginning July 1, 2001, usage of FDG PET for lymphoma has been expanded to include diagnosis, staging and restaging (see section III) of the disease.

A. Effective July 1, 1999, FDG PET is covered for the staging and restaging of lymphoma.

Requirements:

- FDG PET is covered only for staging or follow-up restaging of lymphoma. Claims must include a statement or other evidence of previous diagnosis of lymphoma when used as an alternative to a Gallium scan
- To ensure that the PET scan is properly coordinated with other diagnostic modalities, claims must include the results of concurrent computed tomography (CT) and/or other diagnostic

- In order to ensure that the PET scan is covered only as an alternative to a Gallium scan, no PET scan may be covered in cases where it is done within 50 days of a Gallium scan done by the same facility where the patient has remained during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen. The purpose of this screen is to assure that PET scans are covered only when done as an alternative to a Gallium scan within the same facility. We are aware that, in order to assure proper patient care, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable.

Frequency Limitation for Restaging: PET scans will be allowed for restaging no sooner than 50 days following the last staging PET scan or Gallium scan, unless sufficient evidence is presented to convince the Medicare contractor that the restaging at an earlier date is medically necessary. Since PET scans for restaging are generally done following cycles of chemotherapy, and since such cycles usually take at least 8 weeks, we believe this screen will adequately prevent medically unnecessary scans while allowing some adjustments for unusual cases. In all cases, the determination of the medical necessity for a PET scan for re-staging lymphoma is the responsibility of the local Medicare contractor.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

B. Effective for services performed on or after July 1, 2001, the Medicare program has broadened coverage of FDG PET for the diagnosis, staging and restaging of lymphoma.

Requirements: PET is covered in either/both of the following circumstances:

- Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.
- Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

IX. Coverage of FDG PET for Melanoma

Medicare covered the evaluation of recurrent melanoma prior to surgery when used as an alternative to a Gallium scan, effective July 1, 1999. For services furnished on or after July 1, 2001 FDG PET is

covered for the diagnosis, staging, and restaging of malignant melanoma (see part III). FDG PET is not covered for the use of evaluating regional nodes in melanoma patients.

A. Effective for services furnished July 1, 1999 through June 30, 2001, in the case of patients with recurrent melanoma prior to surgery, FDG PET (when used as an alternative to a Gallium scan) is covered for tumor evaluation.

Frequency Limitations: Whole body PET scans cannot be ordered more frequently than once every 12 months, unless medical necessity documentation, maintained in the beneficiaries medical record, supports the specific need for anatomic localization of possible recurrent tumor within this period.

Limitations: The FDG PET scan is covered only as an alternative to a Gallium scan. PET scans can not be covered in cases where it is done within 50 days of a Gallium scan done by the same PET facility where the patient has remained under the care of the same facility during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen. The purpose of this screen is to assure that PET scans are covered only when done as an alternative to a Gallium scan within the same facility. We are aware that, in order to assure proper patient care, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable to make the determination covered by this provision. Therefore, we will apply this 50-day rule only to PET scans done by the same facility that performed the Gallium scan.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical file at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

B. Effective for services performed on or after July 1, 2001 FDG PET scan coverage for the diagnosis, staging and restaging of melanoma (not the evaluation regional nodes) has been broadened.

Limitations: PET scans are not covered for the evaluation of regional nodes.

Requirements: PET is covered in either/both of the following circumstances:

Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

- **Staging and/or Restaging -** PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical file, as is normal business practice.

X. Coverage of FDG PET for Head and Neck Cancers

Effective for services performed on or after July 1, 2001, Medicare will provide coverage for cancer of the head and neck, excluding the central nervous system (CNS) and thyroid. The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Patients may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Patients that present with cancer of the head and neck are left with two options either to have a neck dissection or to have radiation of both sides of the neck with random biopsies. PET scanning attempts to reveal the site of primary tumor to prevent the adverse effects of random biopsies or unneeded radiation.

Limitations: PET scans for head and neck cancers are not covered for CNS or thyroid cancers (prior to October 1, 2003). Refer to section XIV for coverage for thyroid cancer effective October 1, 2003.

Requirements: PET is covered in either/or both of the following circumstances:

- Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.
- Staging and/or Restaging – PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XI. Coverage of FDG PET for Myocardial Viability

The identification of patients with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization. Diagnostic tests such as FDG PET distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

FDG PET is covered for the determination of myocardial viability following an inconclusive SPECT from July 1, 2001 through September 30, 2002. Only full ring PET scanners are covered from July 1, 2001 through December 31, 2001. However, as of January 1, 2002, full and partial ring scanners are covered.

Beginning October 1, 2002, Medicare covers FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. Studies performed by full and partial ring scanners are covered.

Limitations: In the event that a patient has received a single photon computed tomography test (SPECT) with inconclusive results, a PET scan may be covered. However, if a patient received a FDG PET study with inconclusive results, a follow up SPECT is not covered.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

(See §50-58 of the CIM for SPECT coverage.)

XII. Coverage of FDG PET for Refractory Seizures

Beginning July 1, 2001, Medicare will cover FDG-PET for pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

Limitations: Covered only for pre-surgical evaluation.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XIII. Breast Cancer

Beginning October 1, 2002, Medicare covers FDG PET as an adjunct to other imaging modalities for staging patients with distant metastasis, or restaging patients with locoregional recurrence or metastasis. Monitoring treatment of a breast cancer tumor when a change in therapy is contemplated is also covered as an adjunct to other imaging modalities.

Limitations: Effective October 1, 2002, Medicare continues to have a national non-coverage determination for initial diagnosis of breast cancer and staging of axillary lymph nodes. Medicare coverage for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; and for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated, is only covered as an adjunct to other imaging modalities.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

XIV. Thyroid Cancer

1. Effective for services furnished on or after October 1, 2003, Medicare covers the use of FDG PET for thyroid cancer only for restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin $>10\text{ng/ml}$ and negative I-131 whole body scan performed.

2. All other uses of FDG PET in the diagnosis and treatment of thyroid cancer remain noncovered.

(This NCD last reviewed April 2003.)

XV. Soft Tissue Sarcoma – NOT COVERED

Following a thorough review of the scientific literature, including a technology assessment on the topic, Medicare maintains its national noncoverage determination for all uses of FDG PET for soft tissue sarcoma.

(This NCD last reviewed April 2003.)

XVI. Dementia and Neurogenerative Diseases – NOT COVERED

Following a thorough review of the scientific literature, including a technology assessment on the topic and consideration by the Medicare Coverage Advisory Committee, Medicare maintains its national noncoverage determination for all uses of FDG-PET for the diagnosis and management of dementia or other neurogenerative diseases

(This NCD last reviewed April 2003.)

50-37 NONINVASIVE TESTS OF CAROTID FUNCTION

(Effective for services performed on and after November 15, 1980)

Noninvasive tests of carotid function aid physicians in studying and diagnosing carotid disease. There are a variety of these tests which measure various anatomical and physiological aspects of carotid function, including pressure (systolic, diastolic, and pulse), flow, collateral circulation, and turbulence.

For operational purposes, it is useful to classify noninvasive tests of carotid function into direct and indirect tests. The direct tests examine the anatomy and physiology of the carotid artery, while the indirect tests examine hemodynamic changes in the distal beds of the carotid artery (the orbital and cerebral circulations).

It is important to note that the names of these tests are not standardized. Following are some of the acceptable tests, recognizing that this list is not inclusive and that determinations should be made by local medical consultants:

DIRECT TESTS

Carotid Phonoangiography
Direct Bruit Analysis
Spectral Bruit Analysis
Doppler Flow Velocity
Ultrasound Imaging including Real Time
B-Scan and Doppler Devices

INDIRECT TESTS

Periorbital Directional Doppler Ultrasonography
Oculoplethysmography
Ophthalmodynamometry

50-38 ENDOTHELIAL CELL PHOTOGRAPHY

(Effective for services rendered on and after August 19, 1983)

Endothelial cell photography involves the use of a specular microscope to determine the endothelial cell count. It is used by ophthalmologists as a predictor of success of ocular surgery or certain other ocular procedures. Endothelial cell photography is a covered procedure under Medicare when reasonable and necessary for patients who meet one or more of the following criteria:

- o Have slit lamp evidence of endothelial dystrophy (cornea guttata),
- o Have slit lamp evidence of corneal edema (unilateral or bilateral),
- o Are about to undergo a secondary intraocular lens implantation,
- o Have had previous intraocular surgery and require cataract surgery,
- o Are about to undergo a surgical procedure associated with a higher risk to corneal endothelium; i.e., phacoemulsification, or refractive surgery (see §35-54 for excluded refractive procedures),
 - o With evidence of posterior polymorphous dystrophy of the cornea or irido-corneal-endothelium syndrome, or
 - o Are about to be fitted with extended wear contact lenses after intraocular surgery.

When a pre-surgical examination for cataract surgery is performed and the conditions of this section are met, if the only visual problem is cataracts, endothelial cell photography is covered as part of the presurgical comprehensive eye examination or combination brief/intermediate examination provided prior to cataract surgery, and not in addition to it. (See §35-44.)

50-39 TELEPHONE TRANSMISSION OF ELECTROENCEPHALOGRAMS

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:

- o Altered consciousness, such as stuporous, semicomatose, or comatose states;
- o Atypical seizure variants in patients experiencing bizarre, distressing symptoms as seen with "spike and wave stupor" or other forms of seizure disorders;
- o Diagnosis of a suspected intracranial tumor;
- o Head injury, where a subdural hematoma may be identified;
- o 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.

50-39.1 AMBULATORY ELECTROENCEPHALOGRAPHIC (EEG) MONITORING (Effective for services performed on or after June 12, 1984)

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.

50-40 STEREOTAXIC DEPTH ELECTRODE IMPLANTATION

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.

50-41 HUMAN TUMOR STEM CELL DRUG SENSITIVITY ASSAYS

Human tumor stem cell drug sensitivity assays involve exposure of human tumor stem cell colonies grown in tissue culture to anticancer drugs and observing for cytotoxic effects. Their purpose is to screen potential anticancer drugs and predict the effects of these drugs on tumors of individual patients, to allow the selection of the most effective drug or drugs for that patient. Human tumor drug sensitivity assays are considered experimental, and therefore, not covered under Medicare at this time.

The Fluorescent Cytoprint Assay, a miniaturized organ culture system for cancer chemosensitivity testing, allows for qualitative visual estimation of cell kill using low power microscopy and a noncytotoxic fluorescence probe for cell viability. The clinical application of the assay, based on testing in tumor microorgans rather than in clones derived from single cells, is considered experimental, and therefore, not covered under Medicare at this time.

50-42 AMBULATORY BLOOD PRESSURE MONITORING

Ambulatory blood pressure monitoring (ABPM) involves the use of a non-invasive device which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by the physician. ABPM must be performed for at least 24 hours to meet coverage criteria.

ABPM is only covered for those patients with suspected white coat hypertension. Suspected white coat hypertension is defined as 1) office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; 2) at least two documented blood pressure measurements taken outside the office which are <140/90 mm Hg; and 3) no evidence of end-organ damage. The information obtained by ABPM is necessary in order to determine the appropriate management of the patient. ABPM is not covered for any other uses. In the rare circumstance that ABPM needs to be performed more than once in a patient, the qualifying criteria described above must be met for each subsequent ABPM test.

For those patients that undergo ABPM and have an ambulatory blood pressure of <135/85 with no evidence of end-organ damage, it is likely that their cardiovascular risk is similar to that of normotensives. They should be followed over time. Patients for which ABPM demonstrates a blood pressure of >135/85 may be at increased cardiovascular risk, and a physician may wish to consider antihypertensive therapy.

(This NCD last reviewed January 16, 2003)

50-43 DIGITAL SUBTRACTION ANGIOGRAPHY

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

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

Reimbursement for DSA should not exceed, and may be less than, that being paid for conventional angiographic techniques. (See CMS Pub. 14-3, §5242 for reasonable charge instructions.)

50-44 BONE (MINERAL) DENSITY STUDIES--Effective for services rendered on or after March 4, 1983.

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 non-invasive 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:

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.

50-45 LYMPHOCYTE MITOGEN RESPONSE ASSAYS--FOR SERVICES PERFORMED ON OR AFTER MAY 16, 1983.

The lymphocyte mitogen response assay measures the immune response of patient peripheral blood lymphocytes. It is a covered test under Medicare when it is medically necessary to assess lymphocytic function in diagnosed immunodeficiency diseases and to monitor immunotherapy.

It is not covered when it is used to monitor the treatment of cancer, because its use for that purpose is experimental.

50-46 TRANSILLUMINATION LIGHT SCANNING, OR DIAPHANOGRAPHY--NOT COVERED.

While transillumination light scanning, or diaphanography, for use in detection of cancer and other diseases of the breast, appears safe, the usefulness of this instrumentation, when compared to existing modes of cancer and other breast disease detection, has not clearly been established. Further study of this technology is needed to determine its role in breast cancer diagnosis. Program payment may not be made for this procedure at this time.

50-47 CARDIOINTEGRAM (cm) AS AN ALTERNATIVE TO STRESS TEST OR THALLIUM STRESS TEST--NOT COVERED.

A cardiotracing device consists of a microcomputer which receives output from a standard electrocardiogram (EKG) and transforms it to produce a graphic representation of heart electrophysiologic signals. This procedure is used primarily as a substitute for Exercise Tolerance Testing with Thallium Imaging in patients for whom a resting EKG may be inadequate to identify changes compatible with coronary artery disease. Because this device is still considered investigational pending additional data on its clinical efficacy/sensitivity and value as a diagnostic tool, program payment may not be made for its use at this time.

50-48 PORTABLE HAND-HELD X-RAY INSTRUMENT (EFFECTIVE FOR SERVICES PERFORMED ON OR AFTER November 6, 1986.)

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

50-49 COMPUTER ENHANCED PERIMETRY—(EFFECTIVE FOR SERVICES RENDERED ON OR AFTER FEBRUARY 15, 1984).

Computer enhanced perimetry involves the use of a micro-computer to measure visual sensitivity at preselected locations in the visual field. It is a covered service when used in assessing visual fields in patients with glaucoma or other neuropathologic defects.

50-50 DISPLACEMENT CARDIOGRAPHY

Displacement cardiography, including cardiomography and photokymography, is a noninvasive diagnostic test used in evaluating coronary artery disease.

A. Cardiomography.—(Effective For Services Rendered On Or After October 12, 1988).

Cardiomography is a covered service only when it is used as an adjunct to electrocardiographic stress testing in evaluating coronary artery disease and only when the following clinical indications are present:

- o For male patients, atypical angina pectoris or nonischemic chest pain; or
- o For female patients, angina, either typical or atypical.

B. Photokymography.—NOT COVERED

Photokymography remains excluded from coverage.

50-51 DIAGNOSTIC BREATH ANALYSES.

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 effective for services rendered on and after June 12, 1984.

THE FOLLOWING BREATH TESTS ARE EXCLUDED FROM COVERAGE:

o. Lactulose breath hydrogen for diagnosing small bowel bacterial overgrowth and measuring small bowel transit time, effective for services rendered on and after May 4, 1984.

2 or diagnosing bile acid malabsorption, effective for services rendered on and ~¹³CO f after June 12, 1984.

0 ¹³C0₂ for diagnosing fat malabsorption, effective for services rendered on and after June 12, 1984.

50-52 SEROLOGIC TESTING FOR ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) (Effective for services performed on or after August 12, 1987.)

Serologic testing is employed to detect antibodies to the AIDS virus, which is currently identified by the term "human immunodeficiency virus (HIV)." The virus originally was named "human T-cell lymphotropic virus, type III (HTLV-III), a term that remains in common usage.

Antibodies may be detected by a variety of immunoassay techniques, the most common being an enzyme-linked immunosorbent assay (ELISA). When an assay is reactive on initial testing, it should be repeated on the same specimen. A more specific test, (Western blot, immunofluorescent assay) is usually performed following repeatedly reactive ELISA results.

These tests may be covered when performed to help determine a diagnosis for symptomatic patients. They are not covered when furnished as part of a screening program for asymptomatic persons.

NOTE: Two enzyme-linked immunosorbent assay (ELISA) tests that were conducted on the same specimen must both be positive before Medicare will cover the Western blot test.

50-53 FOOD ALLERGY TESTING AND TREATMENT--NOT COVERED--(Effective for services furnished on or after October 31, 1988.)

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.

50-54 CARDIAC OUTPUT MONITORING BY ELECTRICAL BIOIMPEDANCE--COVERED (Effective for services performed on or after July 1, 1999)

Cardiac monitoring using electrical bioimpedance, a form of plethysmography, is covered, effective for services furnished on or after July 1, 1999, for the uses and conditions described below. Contractors should be aware that this technology is in the process of being proven for additional uses. Therefore, the uses below represent the current situation. Contractors may cover additional uses when they believe there is sufficient evidence of the medical effectiveness of such uses.

These devices utilize electrical bioimpedance to noninvasively produce hemodynamic measurements of cardiac output, specifically, stroke volume, contractility, systemic vascular resistance and thoracic fluid content. These devices are covered for the following uses:

1. Noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease;
2. Differentiation of cardiogenic from pulmonary causes of acute dyspnea;
3. Optimization of atrioventricular interval for patient with A/V sequential cardiac pacemakers;
4. Patients with need of determination for intravenous inotropic therapy;
5. Post heart transplant myocardial biopsy patients; and,
6. Patients with a need for fluid management.

Not covered at this time are the use of such devices for any monitoring of patients with proven or suspected disease involving severe regurgitation of the aorta, or for patients with minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker. Also, these devices do not render accurate measurements in cardiac bypass patients while on a cardiopulmonary bypass machine, but do provide accurate measurements prior to and post bypass pump.

Covered uses of cardiac output monitoring by electrical bioimpedance should be billed using HCPCS code M0302.

50-55 PROSTATE CANCER SCREENING TESTS - COVERED (Effective for services furnished on or after January 1, 2000)

A. General--Section 4103 of the Balanced Budget Act of 1997 provides for coverage of certain prostate cancer screening tests subject to certain coverage, frequency, and payment limitations. Effective for services furnished on or after January 1, 2000. Medicare will cover prostate cancer screening tests/procedures for the early detection of prostate cancer. Coverage of prostate cancer screening tests includes the following procedures furnished to an individual for the early detection of prostate cancer:

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

B. Screening Digital Rectal Examinations--Screening digital rectal examinations (HCPCS code G0102) are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening digital rectal examination was performed). Screening digital rectal examination means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate. This screening must be performed by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or by a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in §1861(aa) and §1861(gg) of the Act) who is authorized under State law to perform the examination, fully knowledgeable about the beneficiary's medical condition, and would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.

C. Screening Prostate Specific Antigen Tests--Screening prostate specific antigen tests (code G0103) are covered at a frequency of once every 12 months for men who have attained age 50 (at least 11 months have passed following the month in which the last Medicare-covered screening prostate specific antigen test was performed). Screening prostate specific antigen tests (PSA) means a test to detect the marker for adenocarcinoma of prostate. PSA is a reliable immunocytochemical marker for primary and metastatic adenocarcinoma of prostate. This screening must be ordered by the beneficiary's physician or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (the term "attending physician" is defined in §1861(r)(1) of the Act to mean a doctor of medicine or osteopathy and the terms "physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife" are defined in §1861(aa) and §1861(gg) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible for using the results of any examination (test) performed in the overall management of the beneficiary's specific medical problem.

50-56 HOME PROTHROMBIN TIME INTERNATIONAL NORMALIZED RATIO (INR) MONITORING FOR ANTICOAGULATION MANAGEMENT

Use of the International Normalized Ratio (INR) allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's prothrombin time compared to the mean prothrombin time for a group of normal individuals. Maintaining patients within the therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.

Home prothrombin monitoring with the use of INR devices is covered only for patients with mechanical heart valves. The monitor and the home testing must be prescribed by a treating physician as provided at 42 C.F.R. 410.32 (a) and the following requirements must be met:

1. The patient must have been anticoagulated for at least three months prior to use of the home INR device;
2. The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
3. Self-testing with the device should not occur more frequently than once a week.

50-57.1 CURRENT PERCEPTION THRESHOLD/SENSORY NERVE CONDUCTION THRESHOLD TEST (sNCT) NONCOVERED

The Current Perception Threshold/Sensory Nerve Conduction Threshold (sNCT) test is a diagnostic test used to diagnose sensory neuropathies. The device is a noninvasive test that uses transcutaneous electrical stimuli to evoke a sensation. There is insufficient scientific or clinical evidence to consider this device reasonable and necessary within the meaning of Section 1862(a)(1)(A) of the law and will not be covered by Medicare.

50-58 SINGLE PHOTON EMISSION TOMOGRAPHY – COVERED

Single-photon emission computed tomography (SPECT) acquires information on the concentration of radionuclides introduced into the patient's body. It is useful in the diagnosis of several clinical conditions including:

- stress fracture
- spondylosis
- infection (e.g., discitis)
- tumor (e.g., osteoid osteoma)
- analyze blood flow to an organ, as in the case of myocardial viability
- differentiate ischemic heart disease from dilated cardiomyopathy.

Frequency limitations: Contractor discretion.

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

50-59 PERCUTANEOUS IMAGE-GUIDED BREAST BIOPSY

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

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

A. Nonpalpable Breast Lesions--

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

B. Palpable Breast Lesions--

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

55 DIALYSIS EQUIPMENT

55-1 WATER PURIFICATION AND SOFTENING SYSTEMS USED IN CONJUNCTION WITH HOME DIALYSIS

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

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

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

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

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

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

B. Water Softening System.—Except as indicated below, a water softening system used in conjunction with home dialysis is excluded from coverage under Medicare as not being reasonable and necessary within the meaning of S1862(a)(1) of the law. Such a system, in conjunction with a home dialysis unit, does not adequately remove the hazardous heavy metal contaminants (such as arsenic) which may be present in trace amounts.

A water softening system may be covered when used to pretreat water to be purified by a reverse osmosis (RO) unit for home dialysis where:

- o The manufacturer of the RO unit has set standards for the quality of water entering the RO (e.g., the water to be purified by the RO must be of a certain quality if the unit is to perform as intended);

- o The patient's water is demonstrated to be of a lesser quality than required; and
- o The softener is used only to soften water entering the RO unit, and thus, used only for dialysis. (The softener need not actually be built into the RO unit, but must be an integral part of the dialysis system.)

C. Developing Need When a Water Softening System is Replaced with a Water Purification Unit in an Existing Home Dialysis System.—The medical necessity of water purification units must be carefully developed when they replace water softening systems in existing home dialysis systems. A purification system may be ordered under these circumstances for a number of reasons. For example, changes in the medical community's opinions regarding the quality of water necessary for safe dialysis may lead the physician to decide the quality of water previously used should be improved, or the water quality itself may have deteriorated. Patients may have dialyzed using only an existing water softener previous to Medicare ESRD coverage because of inability to pay for a purification system. On the other hand, in some cases, the installation of a purification system is not medically necessary. Thus, when such a case comes to your attention, ask the physician to furnish the reason for the changes. Supporting documentation, such as the supplier's recommendations or water analysis, may be required. All such cases should be reviewed by your medical consultants.

Cross—refer: Intermediary Manual, SS3113, 3643 (item ic); Carriers Manual,

SS2100, 2100.2 2130, 2105 (item ic); Hospital Manual, S235.

55-2 PERIDEX CAPD FILTER SET -- NOT COVERED

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

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

55-3 ULTRAFILTRATION MONITOR

(Effective for services performed on and after July 11, 1983.)

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

Covered:

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

Not Covered:

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