indicated or the offices of the Board of Governors not later than September 8, 1989.

A. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Fourth Financial Corporation,* Wichita, Kansas; to merge with Southwest Financial Corporation, Garden City, Kansas, and thereby indirectly acquire The Garden National Bank, Garden City, Kansas.

In connection with this application, Applicant proposes to engage in credit-related insurance pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 15, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-19576 Filed 8-18-89; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Advisory Committee Meeting in September

AGENCY: Alcohol, Drug Abuse, and Mental Health Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for the forthcoming meeting of an agency extramural science advisory board in the month of September 1989. The Board will discuss current research program activities. Attendance by the public will be limited to space available.

Committee Name: Extramural Science Advisory Board, NIAAA.

Date and Time: September 12: 1:00 p.m.–6:00 p.m.; September 13: 9:00 a.m.–5:00 p.m.

Place: National Institutes of Health, Building 31, Conference Room 9, 9000 Rockville Pike, Bethesda, MD 20892.

Status of Meeting: Open.

Contact: Michael J. Lewis, Parklawn Building, Room 16C–26, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–6106.

Purpose: The Advisory Board advises the Secretary, Department of Health and Human Services, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, and the Director, National Institute on Alcohol Abuse and Alcoholism, based on an ongoing review of the direction, scope, balance, and emphasis of the Institute's extramural science program.

Substantive program information may be obtained from the contract person listed above. The NIAAA Advisory Board Staff Coordinator, Ms. Nancy Colladay, Room 16C–23, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857 will furnish summaries of the meeting and a roster of committee members upon request.

Dated: August 15, 1989.

Peggy W. Cockrill,

Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 89-19630 Filed 8-18-89; 8:45 am]

BILLING CODE 4160-20-M

Centers for Disease Control

In Vitro Systems for Human Biological Monitoring; National Institute for Occupational Safety and Health Meeting

The following meeting will be convened by the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control (CDC).

Name: In Vitro Systems for Human Biological Monitoring.

Time and Date: 9:00 a.m.–3:00 p.m.—September 5, 1989.

Place: Robert A. Taft Laboratories, 4676 Columbia Parkway, Auditorium, Cincinnati, Ohio 45226–1998.

Status: Open to the public, limited only by the space available.

Purpose: To review and discuss in vitro systems for the generation of biotransformation data that may be used in the selection of biomarkers of human exposure to chemical xenobiotics.

Contact Person: Donald E. Richards, NIOSH, CDC, Robert A. Taft Laboratories (C23), 4676 Columbia Parkway, Cincinnati, Ohio 45226–1998, Telephone: Commercial: (513) 533–8192, FTS: 684–8192.

Dated: August 15, 1989.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 89-19561 Filed 8-18-89; 8:45 am]

BILLING CODE 4160-19-M

Advisory Committee for Injury Prevention and Control; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control (CDC) announces the following Committee meeting:

Name: CDC Advisory Committee on Injury Prevention and Control.

Time and Date: 9:00 a.m.–5:00 p.m.—September 6, 1989, 9:00 a.m.–3:00 p.m.—September 7, 1989.

Place: Koger Center, Davidson Building, Room 2060, 2858 Woodcock Boulevard, NE, Atlanta, Georgia 30341.

Status: Open to the public, limited only by the space available

Purpose: The Committee will make recommendations on policy, strategy, objectives, and priorities including the balance and mix of intramural and extramural research; advise on the development of a national plan for injury prevention and control and the development of new technologies and their application; and review progress toward injury prevention and control.

Matters to be Discussed: The Committee will discuss its purpose and goals, and map out its agenda for the next 12 months. The meeting will include an orientation to CDC programs and activities related to the prevention and control of injuries.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Mark Rosenberg, M.D., Director, Division of Injury Epidemiology and Control, Center for Environmental Health and Injury Control, CDC, 1600 Clifton Road NE., Mailstop F–36, Atlanta, Georgia 30333, telephone: FTS: 236–4690; Commercial: 404/488–4690.

Dated: August 15, 1989.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 89-19563 Filed 8-18-89; 8:45 am]

BILLING CODE 4160-18-M

Board of Scientific Counselors (BSC); National Institute for Occupational Safety and Health; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control (CDC) announces the following Committee meeting:

Name: NIOSH Board of Scientific Counselors.

Time and Date: 1:00 p.m.–5:00 p.m.—September 11, 1989, 9:00 a.m.–4:30 p.m.—September 12, 1989.

Place: Newport Beach Marriot Hotel, 900 Newport Center Drive, Newport Beach, California.

Status: Closed: 3:45 p.m.–5:00 p.m., September 11, 1989. All other portions of the meeting are open to the public, limited only by the space available.

Purpose: The Board is charged with advising the Director of NIOSH on the

scientific quality and efficacy of the Institute's research.

Contact Person: Roy M. Fleming, Sc.D., Executive Secretary, BSC, NIOSH, CDC, Bldg. 1, Room 3057, D30, 1600 Clifton Road, NE., Atlanta, Georgia 30333, Telephone: Commercial: (404) 639-3343, FTS: 236-3343.

Agenda: Agenda items for the meeting will include announcements, consideration of minutes of the previous meeting, a report from the Director of NIOSH, site visit reports, surveillance subcommittee report, Gouverneur Talc subcommittee report, research needs subcommittee report, discussions of NIOSH research initiatives, and future Board activities. Beginning at 3:45 p.m. through 5:00 p.m., September 11, the Board will discuss certain matters the public disclosure of which would constitute a violation of sections 552b(c)(6) and/or 552b(c)(9)(B) of Title 5 U.S. Code related to personal privacy. Therefore, pursuant to said provisions and the determination of the Acting Director, CDC, this portion of the meeting will not be open to the public.

Agenda items are subject to change as priorities dictate.

The portions of the meeting so indicated are open to the public for observation and participation. Anyone wishing to make an oral presentation should notify the contact person listed above as soon as possible before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the presentation. Oral presentations will be scheduled at the discretion of the Chairperson and as time permits.

A roster of members and other relevant information regarding the meeting may be obtained from the contact person listed above.

Dated: August 15, 1989.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 89-19562 Filed 8-18-89; 8:45 am]

BILLING CODE 4160-19-M

National Committee on Vital and Health Statistics Subcommittee on Minority Health Statistics; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Minority Health Statistics established pursuant to 42 U.S.C. 242k, section 306(k)(2), of the Public Health Service Act, as amended, announces the following Subcommittee meeting.

Name: NCVHS Subcommittee on Minority Health Statistics.

Time and Date: 10:00 a.m.-3:00 p.m., September 6, 1989.

Place: Room 337A-339A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open.

Purpose: The Subcommittee will develop a 1990 work plan and develop a report on medically indigent issues.

Contact Person: Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, Room 2-12, Center Building, 3700 East West Highway, Hyattsville, Maryland 20782, telephone (301) 436-7050

Dated: August 15, 1989.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 89-19564 Filed 8-18-89; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following district consumer exchange meeting: San Francisco District Office, chaired by Ronald M. Johnson, District Director. The topic to be discussed is food labeling.

DATES: Thursday, September 21, 1989, 7:30 p.m. to 8:30 p.m.

ADDRESSES: O'Connor Hospital, Medical Office Bldg. Auditorium, 2105 Forest Ave., San Jose, CA 95128.

FOR FURTHER INFORMATION CONTACT: Janet McDonald, Consumer Affairs Officer, Food and Drug Administration, 50 United Nations Plaza, Rm. 526, San Franscisco, CA 94102, 415-556-1364.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's district offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 11, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-19512 Filed 8-18-89; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

[BERC-638-GN]

Medicare Program; National Coverage Decisions

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: General notice.

SUMMARY: This notice lists those current Medicare national coverage decisions which have been issued in the Medicare Coverage Issues Manual (HCFA Pub. 6). These national coverage decisions are also widely distributed through the U.S. Government Printing Office, the National Technical Information Service, and private publishers such as the Commerce Clearing House. From time to time, some of the individual decisions have been published in the **Federal Register**. In this **Federal Register** notice, HCFA is publishing a compilation of these national coverage decisions. We will publish subsequent national coverage decisions in the **Federal Register** on a quarterly basis.

FOR FURTHER INFORMATION CONTACT: Sam Della Vechia, (301) 966-5316.

SUPPLEMENTARY INFORMATION:

I. Process for Making National Coverage Decisions

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare program, a program which pays for health care and related services for 33 million Medicare beneficiaries. Under the Medicare program, the benefits available to eligible beneficiaries are called "covered" services and include those medical supplies, treatment procedures and technologies that often have been referred to as "items." Throughout this notice, the term "services" refers to both services and items.

Except in circumstances specified in the statute, Medicare program funds cannot be used to pay for services furnished to Medicare beneficiaries that are not covered under the Social Security Act (the Act). Additionally, section 1862(a)(1)(A) of the Act prohibits payment under the Medicare program for any expense incurred for services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

The coverage decisions listed in the Medicare Coverage Issues Manual and this notice constitute "national coverage determination[s]," as provided for in

sections 1869(b)(3) and 1871(a)(2) of the Act. HCFA uses the terms "national coverage decision" and "national coverage determination" interchangeably. These sections of the Act address issuance, publication, and administrative and judicial review of national coverage decisions. In the absence of national coverage decisions, local Medicare contractors have the discretion to determine whether a particular service that meets all other requirements for coverage appears to be reasonable and necessary and therefore covered under Medicare.

The process by which national coverage decisions would be made and the criteria for these decisions are described in a proposed rule published in the **Federal Register** on January 30, 1989 (54 FR 4302). (We are currently considering public comments on that proposed rule and are developing the final rule that will be published in the **Federal Register**. The statutory basis for all national coverage decisions in the Medicare Coverage Issues Manual is section 1862(a)(1)(A) of the Act (the "not reasonable and necessary" exclusion) unless otherwise specified. If a decision to exclude or limited a service is imposed under another statutory authority, that statutory basis for exclusion or limitation constitutes the sole basis for that decision, unless otherwise specified. The section 1862(a)(1)(A) exclusion is applicable only if no other statutory basis for exclusion applies.

In addition to the national coverage decisions that have been published in the Medicare Coverage Issues Manual (HCFA Pub. 6), others have been published in Part 3 of the Intermediary (HCFA Pub. 13–3) and Carriers (HCFA Pub. 14–3) manuals, as well as in regulations, rulings and **Federal Register** notices. Many of these same national coverage decisions also have been repeated in the program manuals issued to Medicare providers. Those manuals include: Outpatient Physical Therapy Provider and CORF (HCFA Pub. 9), Hospital (HCFA Pub. 10), Home Health Agency (HCFA Pub. 11), SNF (HCFA Pub. 12), Hospice (HCFA Pub. 21), and Renal Dialysis Facility (HCFA Pub. 29).

II. Purpose of this General Notice

This notice lists those current Medicare national coverage decisions issued in the Medicare Coverage Issues Manual, which we have included as an appendix. All future revisions to the Medicare Coverage Issues Manual will be published in the Federal Register as general notices on a quarterly basis.

An individual or organization interested in receiving the Medicare Coverage Issues Manual (HCFA Pub. 6) and revisions to it may purchase a subscription by contacting either:

Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (Telephone (202) 783–3238)

or

National Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, (Telephone (703) 487–4630).

Authority: Section 1102, 1862, 1869 and 1871 of the Social Security Act (42 U.S.C. 1302, 1395(ff), 1395(hh) and 1395(y)).

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare—Hospital Insurance and Program 13.774, Medicare Supplementary Medical Insurance).

Dated: July 13, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.

Appendix—Medicare Coverage Issues Manual

Foreword

A. *Function of the Medicare Coverage Issues Manual.*—The Coverage Issues Manual sets forth whether specific medical items, services, treatment procedures or technologies can be paid for under Medicare. National coverage decisions have been made on the items addressed in this manual. All decisions that items, services, etc. are not covered are based on § 1862(a)(1) of the Social Security Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the sole authority for denial. Where an item, service, etc. is stated to be *covered,* but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on § 1862(a)(1) of the Act. Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in this Manual, the Intermediary Manual, or the Carriers Manual, it is up to the Medicare contractor to make the coverage decision, in consultation with its medical staff, and with the Health Care Financing Administration (HCFA) when appropriate, based on the law, regulations, rulings and general program instruction.

B. *Contents and Organization.*—

1. *Contents.*—The statutory and policy framework within which coverage decisions are made may be found in title XVIII of the Social Security Act, and in Medicare regulations, rulings, and other instructions of HCFA issued under its authority, including this manual and the Intermediary and Carriers Manuals. Certain sections may include cross-references to specific sections of the statute, regulations, or other Medicare manuals.

The coverage decisions in the manual will be kept current, based on the most recent medical and other scientific and technical advice available to HCFA.

2. *Organization.*—The material is organized by categories, e.g., Medical Procedures, Supplies, Diagnostic Services. A Table of Contents is provided at the beginning of the manual designating coverage decision categories. Each subject discussed within the category is listed and identified by a number.

Revisions to the manual are issued through new pages; the reader is not asked to pencil-in changes in the text. Changed material will be indicated in the left margin of a page in the following manner:

Line on which change begins.

Line on which change ends.

The revision transmittal sheet identifies new material and summarizes the principal changes. When a change in policy or procedure is involved, the background and effective date for the change is provided. If, at a later date, you wish to refer to the background explanation given on a transmittal sheet, you can identify the transmittal by its number which appears on each manual page.

C. *Use of the Revision Transmittal Check Sheet.*—Immediately after the title page, there is a check sheet on which receipt of revisions can be recorded. Revised manual transmittals should be filed in transmittal number order to avoid discarding a more recent page in favor of an older one.

If it appears that you have not received a particular transmittal, allow 10 working days after receipt of a higher numbered transmittal before requesting a transmittal that is missing. Transmittals are not always distributed in strict numerical sequence.

D. *Effective Dates for Medicare Coverage Issues Manual Issuances.*—Manual transmittals specify whether the material involves a new policy or procedure, a change, or simply a clarification of existing policies or procedures. For a new or changed policy or procedure, the transmittals and the manual text specify the effective date. It usually carries prospective dates. However, a policy or procedural issuance which corrects a prior

instruction may be given retroactive effect, as specified on the transmittal. A clarification is intended to improve the understanding of policies/procedures that are already in effect, and an effective date is not specified.

Coverage Issues

Medical Procedures	
Colonic Irrigation	35–1
Manipulation	35–2
Heat Treatment, Including the Use of Diathermy and Ultrasound for Pulmonary Conditions	35–3
Ultrasonic Surgery	35–4
Cellular Therapy	35–5
Thermogenic Therapy	35–6
Carotid Body Resection/Carotid Body Denervation	35–7
Acupuncture	35–8
Phaco-Emulsification Procedure-Cataract Extraction	35–9
Hyperbaric Oxygen Therapy	35–10
Sterilization	35–11
Plastic Surgery to Correct "Moon Face"	35–12
Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections With Sclerosing Agents	35–13
Consultations With a Beneficiary's Family and Associates	35–14
Postural Drainage Procedures and Pulmonary Exercises	35–15
Vitrectomy	35–16
Induced Lesions of Nerve Tracts	35–17
Electrosleep Therapy	35–18
Intravenous Histamine Therapy	35–19
Treatment of Motor Function Disorders With Electric Nerve Stimulation	35–20
Inpatient Hospital Pain Rehabilitation Programs	35–21
Outpatient Hospital Pain Rehabilitation Programs	35–21.1
Inpatient Hospital Stays for the Treatment of Alcoholism	35–22
Outpatient Hospital Services for Treatment of Alcoholism	35–22.1
Treatment of Drug Abuse (Chemical Dependency)	35–22.2
Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic	35–22.3
Chemical Aversion Therapy for Treatment of Alcoholism	35–23
Electrical Aversion Therapy for Treatment of Alcoholism	35–23.1
Treatment of Impotency	35–24
Cardiac Rehabilitation Programs	35–25
Treatment of Obesity	35–26
Supplemented Fasting	35–26.1
Biofeedback Therapy	35–27
Oxygen Treatment of Inner Ear/Carbon Therapy	35–29
Blood Platelet Transfusions and Bone Marrow Transplantation	35–30
Treatment of Decubitus Ulcers	35–31
Vertebral Artery Surgery	35–32
Intestinal By-Pass Surgery	35–33
Fabric Wrapping of Abdominal Aneurysms	35–34
Therapeutic Embolization	35–35

Coverage Issues—Continued

Extraintracranial Artery Bypass (EIAB) Surgery in the Treatment of Strokes	35–37
Ultrafiltration, Hemoperfusion and Hemofiltration	35–38
Intraocular Photography	35–39
Gastric Bypass Surgery for Obesity	35–40
Diathermy and Diapulse Treatment	35–41
Withdrawal Teatments for Narcotic Addictions	35–42
Esophageal Speech Training	35–43
General Anesthesia in Cataract Surgery	35–44
Cardiac Catheterization Performed in Other Than A Hospital Setting	35–45
Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy	35–46
Breast Reconstruction Following Mastectomy	35–47
Osteogenic Stimulation	35–48
Hyperthermia for Teatment of Cancer	35–49
Cochleostomy with Neurovascular Transplant for Meniere's Disease	35–50
Hemodialysis for Treatment of Schizophenia	35–51
Laser Procedures	35–52
Liver Transplantation	35–53
Refractive Keratoplasty	35–54
Transvenous (Catheter) Pulmonary Embolectomy	35–55
Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders	35–56
Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature	35–57
Electroencephalographic Monitoring During Open-Heart Surgery	35–57.1
Thoracic Duct Drainage (TDD) in Renal Transplants	35–58
Endoscopy	35–59
Therapeutic Pheresis (Apheresis)	35–60
Transsexual Surgery	35–61
Invasive Intracranial Pressure Monitoring	35–62
Tinnitus Masking	35–63
Chelation Therapy for Treatment of Atherosclerosis	35–64
Gastric Freezing	35–65
Treatment of Psoriasis	35–66
Melodic Intonation Therapy	35–67
Anti-Gastroesophageal Reflux Implantation	35–69
Closed-Loop Blood Glucose Control Device (CBGCD)	35–70
Nonselective (Random) Transfusions and Living-Related Donor Specific Transfusions (DST in Kidney Transplantation	35–71
Electrotherapy for Treatment of Facial Nerve Paralysis (Bell's Palsy)	35–72
Injection Sclerotherapy for Esophageal Variceal Bleeding	35–73
External Counterpulsation (ECP)	35–74

Coverage Issues—Continued

Intraoperative Ventricular Mapping	35–75
Neuromuscular Electrical Stimulation (NMES) in the Treatment of Disuse Atrophy	35–77
Diagnostic Endocardial Electrical Stimulation (Pacing)	35–78
Anesthesia in Cardiac Pacemaker Surgery	35–79
Treatment of Kidney Stones	35–81
Pancreas Transplants	35–82
24-Hour Ambulatory Esophageal pH Monitoring	35–83
Stereotactic Cingulotomy as a Means of Psychosurgery	35–84
Implantation of Automatic Defibrillators	35–85
Gastric Balloon for Treatment of Obesity	35–86
Heart Transplants	35–87
Extracorporeal Photopheresis	35–88
Supplies—Drugs	
L-Dopa	45–1
Insulin Syringe	45–3
Vitamin B–12 Injections to Strengthen Tendons, Ligaments, Etc., of the Foot	45–4
Hydrophilic Contact Lens for Corneal Bandage	45–7
Laetril and Related Substances	45–10
Autogenous Epidural Blood Graft	45–11
Porcine Skin and Gradient Pressure Dressing	45–12
Physician's Office Within an Institution-Coverage of Services and Supplies Incident to a Physician's Services	45–15
Certain Drugs Distributed by the National Cancer Institute	45–16
Transfer Factor for Treatment of Multiple Sclerosis	45–17
Granulocyte Transfusions	45–18
Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain	45–19
Ethylenediamine-Tetra-Acetic Acid (EDTA) Chelation Therapy for Treatment of Atherosclerosis	45–20
Scalp Hypothermia during Chemotherapy to Prevent Hair Loss	45–21
Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine)	45–22
Dimethyl Sulfoxide (DMSO)	45–23
Anti-inhibitor Coagulant Complex (AICC)	45–24
Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)	45–25
Diagnostic Services	
Cardiac Pacemaker Evaluation Services	50–1
Cytotoxic Food Tests	50–2
His Bundle Study	50–3
Gravlee Jet Washer	50–4
Thermography	50–5
Plethysmography	50–6
Ultrasound Diagnostic Procedures	50–7

Coverage Issues—Continued

Consulation Service Rendered by a Podiatrist in a Skilled Nursing Facility	50–8
Gastrophotography	50–9
Vabra Aspirator	50–10
Computerized Tomography	50–12
Magnetic Resonance Imaging	50–13
Electrocardiographic Services	50–15
Hemorheograph	50–16
Laboratory Tests—CRD Patients	50–17
Electron Microscopes	50–18
Pronouncement of Death	50–19
Pap Smears	50–20
Mammograms	50–21
Challenge Ingestion Food Testing	50–22
Histocompatability Testing	50–23
Hair Analysis	50–24
Esophageal Manometry	50–25
Dental Examination Prior to Kidney Transplantation	50–26
Xenon Scan	50–27
Hospital and SNF Admission Diagnostic Procedures	50–28
Cytogenetic Studies	50–29
Nuclear Radiology Procedures	50–30
Evoked Response Tests	50–31
Percutaneous Transluminal Angioplasty (PTA) in the Treatment of Arteriosclerotic Obstructions in the Lower Extremities	50–32
Percutaneous Transluminal Coronary Angioplasty (PTCA) in the Treatment of Stenotic Lesions of a Single Coronary Artery	50–32.1
Percutaneous Transluminal Angioplasty (PTA) in the Treatment of Stenotic Lesions of the Renal Arteries	50–32.2
Percutaneous Transluminal Angioplasty (PTA) in the Treatment of Obstructive Lesions of the Aortic Arch Vessels	50–32.3
Percutaneous Transluminal Angioplasty (PTA) in the Treatment of Obstructive Lesions of Arteriovenous Dialysis Fistulas	50–32.4
Uroflowmetric Evaluations	50–33
Obsolete or Unreliable Diagnostic Tests	50–34
Sweat Test	50–35
Positron Emission Transverse Tomography (PETT) Scans	50–36
Noninvasive Tests of Carotid Function	50–37
Endothelial Cell Photography	50–38
Telephone Transmission of Electroencephalograms	50–39
Ambulatory Electroencephalographic (EEG) Monitoring	50–39.1
Stereotaxic Depth Electrode Implanatation	50–40
Human Tumor Stem Cell Drug Sensitivity Assays	50–41
Ambulatory Blood Pressure Monitoring with Fully and Semi-Automatic (Patient-Activated) Portable Monitor	50–42
Digital Subtraction Angiography	50–43
Bone (Mineral) Density Studies	50–44
Lymphocyte Mitogen Response Assays	50–45
Transillumination Light Scanning, or Diaphanography	50–46

Coverage Issues—Continued

Cardiointegram (CIG) as an Alternative to Stress Test or Thallium Stress Test	50–47
Portable Hand-Held X-Ray Instrument	50–48
Computer Enhanced Perimetry	50–49
Displacement Cardiography	50–50
Diagnostic Breath Analyses	50–51
Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS)	50–52
Food Allergy Testing and Treatment	50–53
Dialysis Equipment	
Water Purification and Softening Systems Used In Conjunction with Home Hemodialysis	55–1
Peridex CAPD Filter Set	55–2
Ultrafiltration Monitor	55–3
Durable Medical Equipment	
White Cane for Use by a Blind Person	60–3
Home Use of oxygen	60–4
Power-Operated Vehicles that may be used as Wheelchairs	60–5
Specially Sized Wheelchairs	60–6
Self-Contained Pacemaker Monitors	60–7
Seat Lift	60–8
Durable Medical Equipment Reference List	60–9
Home Blood Glucose Monitor	60–11
Infusion Pumps	60–14
Safety Roller	60–15
Lymphedema Pumps	60–16
Continuous Positive Airway Pressure	60–17
Hospital Beds	60–18
Prosthetic Devices	
Hydrophilic Contact Lenses	65–1
Electrical Continence Aid	65–2
Scleral Shell	65–3
Carotid Sinus Nerve Stimulator	65–4
Electronic Speech Aids	65–5
Cardiac Pacemakers	65–6
Intraoclar Lenses (IOLs)	65–7
Electrical Nerve Stimulators	65–8
Mechnical/Hydraulic Incontinence Control Devices	65–9
Enteral and Parenteral Nutritional Therapy Covered as a Prosthetic Device	65–10
Parenteral Nutrition Therapy	65–10.1
Enteral Nutrition Therapy	65–10.2
Nutritional Supplementation	65–10.3
Bladder Stimulators (Pacemakers)	65–11
Phrenic Nerve Stimulator	65–13
Cochlear Implantation	65–14
Artificial Hearts and Related Devices	65–15
Tracheostomy Speaking Valve	65–16
Braces—Trusses—Artificial Limbs and Eyes	
Corset Used as a Hernia Support	70–1
Sykes Hernia Control	70–2
Prosthetic Shoe	70–3
Patient Education Programs	
Institutional and Home Care Patient Education Programs	80–1

Coverage Issues—Continued

Nursing Services	
Home Health Visits to a Blind Diabetic	90–1
Home Health Nurses' Visits to Patients Requiring Heparin Injections	90–2

35 MEDICAL PROCEDURES

35–1 COLONIC IRRIGATION—NOT COVERED

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

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

35–2 MANIPULATION

A. *Manipulation of the Rib Cage.*—Manual manipulation of the rib cage contributes to the treatment of respiratory conditions such as bronchitis, emphysema, and asthma as part of a regimen which includes other elements of therapy, and is covered only under such circumstances.

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

35–3 HEAT TREATMENT, INCLUDING THE USE OF DIATHERMY AND ULTRASOUND FOR PULMONARY CONDITIONS—NOT COVERED

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

Cross-refer: § 35–41.

35–4 ULTRASONIC SURGERY

Reimbursement may be made for ultrasonic surgery when required in the treatment of patients with severe and recurrent episodes of vertigo due to Meniere's syndrome.

This procedure utilizes a machine which produces ultrasonic waves of high intensity and frequency that selectively irradiate certain portions of the inner ear thereby destroying the tissue. The procedure is usually done under local anesthesia, and requires the services of a surgeon and another individual who is responsible for calibrating the electrical equipment, and who assists in observing certain physical changes (e.g., movement of the eyes, "nystagmus") indicative of inner ear reaction to the ultrasonic destruction. Except in rare instances the desired result is achieved with one treatment. At present, there are two different approaches being used to apply the ultrasound to the inner ear: one through the lateral semicircular canal and, more recently, a simpler approach from a technical viewpoint, through the round window.

35–5 CELLULAR THERAPY—NOT COVERED

Cellular therapy involves the practice of injecting humans with foreign proteins like the placenta or lungs of unborn lambs. Cellular therapy is without scientific or statistical evidence to document its therapeutic efficacy and, in fact, is considered a potentially dangerous practice. Accordingly, cellular therapy is not considered reasonable and necessary within the meaning of section 1862(a)(1) of the law.

35–6 THERMOGENIC THERAPY—NOT COVERED

Thermogenic therapy which is the production of artificial fever has been in use since 1919 in the treatment of certain types of resistant infectious diseases, rheumatoid arthritis and Sydenham's chorea. Regardless of the medium by which the fever is induced, this modality is not scientifically accepted for the treatment of any specific disease. Since the advent of potent antibiotics, the procedure has for all practical purposes been replaced as a mode of treatment. Therefore, thermogenic therapy is not considered reasonable and necessary for the treatment of an illness or injury as required by section 1862(a)(1) of the law. (Of course, where other *covered* services are needed and it would be reasonable and necessary that they be furnished on an inpatient hospital basis, payment would not be excluded for the inpatient stay, notwithstanding the fact that reimbursement may not be made for thermogenic therapy furnished during the hospital stay.)

35–7 CAROTID BODY RESECTION/CAROTID BODY DENERVATION

Carotid body resection is occasionally used to relieve pulmonary symptoms, including asthma, but has been shown to lack general acceptance of the professional medical community. In addition, controlled clinical studies establishing the safety and effectiveness of this procedure are needed. Therefore, all carotid body resections to relieve pulmonary symptoms must be considered investigational and cannot be considered reasonable and necessary within the meaning of section 1862(a)(1) of the law. No program reimbursement may be made in such cases.

There is, however, one instance where carotid body resection has been accepted by the medical community as effective. That instance is when evidence of a mass in the carotid body, *with or without symptoms,* indicates the need for surgery of remove the carotid body tumor.

Denervation of a carotid sinus to treat hypersensitive carotid sinus reflex is another procedure performed in the area of the carotid body. In the case of hypersensitive carotid sinus, light pressure on the upper part of the neck (such as might be experienced when turning or raising one's head) results in symptoms such as dizziness or syncope due to hypotension and slowed heart rate. Failure of medical therapy and continued deterioration in the condition of the patient in such cases may indicate need for surgery. Denervation of the carotid sinus is rarely performed, but when elected as the therapy of choice with the above indications, this procedure may be considered reasonable and necessary.

35–8 ACUPUNCTURE—NOT COVERED

Although acupuncture has been used for thousands of years in China and for decades in parts of Europe, it is a new agent of unknown use and efficacy in the United States. Even in those areas of the world where it has been widely used, its mechanism is not known. Three units of the National Institutes of Health, the National Institute of General Medical Sciences, National Institute of Neurological Diseases and Stroke, and Fogarty International Center have been designed to assess and identify specific opportunities and needs for research attending the use of acupuncture for surgical anesthesia and relief of chronic pain. Until the pending scientific assessment of the technique has been completed and its efficacy has been established, Medicare reimbursement for acupuncture, as an anesthetic or as an analgesic or for other therapeutic purposes may not be made. Accordingly, acupuncture is not considered reasonable and necessary within the meaning of section 1862(a)(1) of the law."

35–9 PHACO–EMULSIFICATION PROCEDURE—CATARACT EXTRACTION

In view of recommendations of authoritative sources in the field of ophthalmology, the subject technique is viewed as an accepted procedure for removal of cataracts. Accordingly, program reimbursement may be made for necessary services furnished in connection with cataract extraction utilizing the phaco-emulsification procedure.

35–10 HYPERBARIC OXYGEN THERAPY

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

A. *Covered Conditions.*—Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) for the following conditions:

1. Acute carbon monoxide intoxication.
2. Decompression illness.
3. Gas embolism.
4. Gas gangrene.
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunction treatment to be used in combination with accepted standard therapeutic measures, when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment, when loss of function, limb, or life is threatened.
7. Meleney ulcers. The use of hyperbaric oxygen in any other type of cutaneous ulcere is not covered.
8. Acute peripheral arterial insufficiency.
9. Preparation and preservation of compromised skin grafts.
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management.
11. Osteoradionecrosis as an adjunct to conventional treatment.

The following use of HBO is covered for services rendered on and after 10/1/82.

12. Soft tissue radionecrosis as an adjunct to conventional treatment.
13. Cyanide poisoning

The following use of HBO is covered for services rendered on or after 2/22/84.

14. Actinomycosis, only as an adjunct to conventional therapy when the

disease process is refractory to antibiotics and surgical treatment.

B. *Noncovered Conditions.*—No program payment may be made for HBO in the treatment of the following conditions:

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

Effective for services rendered on or after September 6, 1984:

22. Acute cerebral edema.

C. *Reasonable Utilization Parameters.*—Make payment where HBO therapy is clinically practical. HBO therapy should not be a replacement for other standard successful therapeutic measures. Depending on the responses of the individual patient and the severity of the original problem, treatment may range from less than 1 week to several months duration, the average being 2 to 4 weeks. Review and document the medical necessity for use of hyperbaric oxygen for more than 2 months, regardless of the condition of the patient, before further reimbursement is made.

D. *Topical Application of Oxygen.*—This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen. (Cross refer: § 35–31.)

35–11 STERILIZATION

A. *Covered Conditions.*—

• Payment may be made only where sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor, removal of diseased ovaries (bilateral oophorectomy), or bilateral orchidectomy in a case of cancer of the prostate. Deny claims when the pathological evidence of the necessity to perform any such procedures to treat an illness or injury is absent; and.

• Sterilization of a mentally retarded beneficiary is covered if it is a necessary part of the treatment of an illness or injury.

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

B. *Noncovered Conditions.*—

• Elective hysterectomy, tubal ligation, and vasectomy, if the stated reason for these procedures is sterilization;

• A sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury within the meaning of § 1862(a)(1) of the law. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant; and

• Sterilization of a mentally retarded person where the purpose is to prevent conception, rather than the treatment of an illness or injury.

35–12 PLASTIC SURGERY TO CORRECT "MOON FACE"—NOT COVERED

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

Cross refer: Intermediary Manual, § 3160; Carriers Manual, § 2329; Hospital Manual, § 260.11.

35–13 PROLOTHERAPY, JOINT SCLEROTHERAPY, AND LIGAMENTOUS INJECTIONS WITH SCLEROSING AGENTS—NOT COVERED

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

35–14 CONSULTATIONS WITH A BENEFICIARY'S FAMILY AND ASSOCIATES

In certain types of medical conditions, incuding when a patient is withdrawn and uncommunicative due to a mental disorder or comatose, the physician may contact relatives and close associates to secure background information to assist in diagnosis and treatment planning. When a physician contacts his patient's relatives or associates for this purpose, expenses of such interviews are properly chargeable as physician's services to the patient on whose behalf the information was secured. If the beneficiary is not an inpatient of a hospital, Part B reimbursement for such an interview is subject to the special limitation on payments for physicians' services in connection with mental, psychoneurotic, and personality disorders.

A physician may also have contacts with a patient's family and associates for purposes other than securing background information. In some cases, the physician will provide counseling to members of the household. Family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition. For example, two situations where family counseling services would be approprite are as follows: (1) where there is a need to observe the patient's interaction with family members; and/or (2) where there is a need to assess the capability of and assist the family members in aiding in the management of the patient. Counseling principally concerned with the effects of the patient's condition on the individual being interviewed would not be reimbursable as part of the physician's personal services to the patient. While to a limited degree, the counseling described in the second situation may be used to modify the behavior of the family members, such services nevertheless are covered because they relate primarily to the management of the patient's problems

and not to the treatment of the family member's problems.

Cross refer: HCFA–Pub. 13–3, § 3212(1); HCFA-Pub. 14–3, §§ 2020, 2470–2476.2; HCFA–Pub. 10, § 160.1

35–15 POSTURAL DRAINAGE PROCEDURES AND PULMONARY EXERCISES

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

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

Cross refer: HCFA-Pub. 13–3, §§ 3112, 3133.9B, 3116; HCFA-Pub. 14–3, § 2050.2

35–16 VITRECTOMY

The conditions for which vitrectomy is indicated are vitreous loss incident to cataract surgery, vitreous opacities due to vitreous hemorrhage or other causes, retinal detachments secondary to vitreous strands, proliferative retinopathy and vitreous retraction.

Medicare payment may be made for (1) Simple vitrectomy (i.e., removal of vitreous humor and replacement with saline whenever there is loss of vitreous), an accepted routine procedure performed incident to cataract surgery, and which prevents postoperative complications, and (2) Complex vitrectomy, as used in cases involving opaque vitreous and secondary retinal detachments.

35–17 INDUCED LESIONS OF NERVE TRACTS

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

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

35–18 ELECTROSLEEP THERAPY—NOT COVERED

Electrosleep therapy consists of the application of short duration, low-amplitude pulses of direct current to the patient's brain via externally placed occipital electrodes. It is commonly used in the treatment of chronic insomnia, anxiety, and depression, but has also been used for psychosomatic disorders such as asthma, spastic colitis, or tension headache, and for organic disorders including essential hypertension. Until scientific assessment of this technique has been completed and its efficacy is established, no program payment may be made for electrosleep therapy.

35–19 INTRAVENOUS HISTAMINE THERAPY

The only accepted and scientifically valid medical use of histamine is diagnostic including tests to assess; the ability of the stomach to secrete acid; the integrity of peripheral sensory nerves (e.g., in leprosy); the circulatory competency in limb extremities; and the presence of a pheochromocytoma. However, there is no scientifically valid clinical evidence that histamine *therapy* is effective for any condition regardless of the method of administration, nor is it accepted or widely used by the medical profession. Therefore, histamine *therapy* cannot be considered reasonable and necessary, and program payment for such therapy should not be made.

35–20 TREATMENT OF MOTOR FUNCTION DISORDERS WITH ELECTRIC NERVE STIMULATION—NOT COVERED

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

Cross refer: §§ 35–27, 65–8

35–21 INPATIENT HOSPITAL PAIN REHABILITATION PROGRAMS

Pain rehabilitation programs are a relatively new and innovative approach to the treatment of intractable pain. The goal of such programs is to give a patient the tools to manage and control his pain, and thereby improve his ability to function independently.

A hospital level pain rehabilitation program is one that employs a coordinated multidisciplinary team to deliver, in a controlled environment, a concentrated program which is designed to modify pain behavior through the treatment of the physiological, psychological, and social aspects of pain. Such programs generally include diagnostic testing, skilled nursing, psychotherapy, structured progressive withdrawal from pain medications, physical therapy and occupational therapy to restore physical fitness (mobility and endurance) to a maximal level within the constraints of a patient's physical disability, and the use of mechanical devices and/or activities to relieve pain or modify a patient's reaction to it (e.g., nerve stimulator, hydrotherapy, massage, ice, systemic muscle relaxation training, and diversional activities). The nurse's responsibility in such pain rehabilitation programs is to observe and assess, on a continuing basis, a patient's condition and response to the program as reflected by his actions while in the nursing unit, and to assure that the atmosphere within the unit is not supportive of pain behavior. The day-to-day activities

involved in carrying out the program are under the general supervision and, as needed, direct supervision of a physician.

Since pain rehabilitation programs of a lesser scope than that described above would raise a question as to whether the program could be provided in a less intensive setting than on an inpatient hospital basis, carefully evaluate such programs to determine whether the program does, in fact, necessitate a hospital level of care. Some pain rehabilitation programs may utilize services and devices which are excluded from coverage, e.g., acupuncture (see § 35–8), biofeedback (see § 35–27), dorsal column stimulator (see § 65–8), and family counseling services (see § 35–14). In determining whether the scope of a pain program does necessitate inpatient hospital care, evaluate only those services and devices which are covered. Although diagnostic tests may be an appropriate part of pain rehabilitation programs, such tests would be covered in an individual case only where they can be reasonably related to a patient's illness, complaint, symptom, or injury and where they do not represent an unnecessary duplication of tests previously performed.

An inpatient program of 4 weeks' duration is generally required to modify pain behavior. After this period it would be expected that any additional rehabilitation services which might be required could be effectively provided on an outpatient basis under an outpatient pain rehabilitation program (see § 35–21.1) or other outpatient program. The first 7–10 days of such an inpatient program constitute, in effect, an evaluation period. If a patient is unable to adjust to the program within this period, it is generally concluded that it is unlikely that the program will be effective and the patient is discharged from the program. On occasions a program longer than 4 weeks may be required in a particular case. In such a case there should be documentation to substantiate that inpatient care beyond a 4-week period was reasonable and necessary. Similarly, where it appears that a patient participating in a program is being granted frequent outside passes, a question would exist as to whether an inpatient program is reasonable and necessary for the treatment of the patient's condition.

An inpatient hospital stay for the purpose of participating in a pain rehabilitation program would be covered as reasonable and necessary to the treatment of a patient's condition where the pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability to function independently has resulted from the pain. Chronic pain patients often have psychological problems which accompany or stem from the physical pain and it is appropriate to include psychological treatment in the multidisciplinary approach. However, patients whose pain symptoms result from a mental condition, rather than from any physical cause, generally cannot be successfully treated in a pain rehabilitation program.

35–21.1 OUTPATIENT HOSPITAL PAIN REHABILITATION PROGRAMS

Some hospitals also provide pain rehabilitation programs for outpatients. In such programs, services frequently are provided in group settings even though they are being furnished pursuant to each patient's individualized plan of treatment.

Coverage of services furnished under outpatient hospital pain rehabilitation programs, including services furnished in group settings under individualized plans of treatment, is available if the patient's pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability by the patient to function independently has resulted from the pain. If a patient meets these conditions and the program provides services of the types discussed in § 35–21 the services provided under the program may be covered. Noncovered services (e.g., vocational counseling, meals for outpatients, or acupuncture) continue to be excluded from coverage, and intermediaries would not be precluded from finding, in the case of particular patients, that the pain rehabilitation program is not reasonable and necessary under § 1862(a)(1) of the law for the treatment of their conditions.

35–22 INPATIENT HOSPITAL STAYS FOR THE TREATMENT OF ALCOHOLISM

A. *Inpatient Hospital Stay for Alcohol Detoxification.*—Many hospitals provide detoxification services during the more actute stages of alcoholism or alcohol withdrawal. When the high probability or occurrence of medical complications (e.g., delirium, confusion, trauma, or unconsciousness) during detoxification for acute alcoholism or alcohol withdrawal necessitates the constant availability of physicians and/or complex medical equipment found only in the hospital setting, inpatient hospital care during this period is considered reasonable and necessary and is therefore covered under the program. Generally, detoxification can be accomplished within 2–3 days with an occasional need for up to 5 days where the patient's condition dictates. This limit (5 days) may be extended in an individual case where there is a need for a longer period for detoxification for a particular patient. In such cases, however, there should be documentation by a physician which substantiates that a longer period of detoxification was reasonable and necessary. When the detoxification needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by section 1862(a)(1) of the law. Following detoxification a patient may be transferred to an inpatient rehabilitation unit or discharged to a residential treatment program or outpatient treatment setting.

B. *Inpatient Hospital Stay for Alcohol Rehabilitation.*—Hospitals may also provide structured inpatient alcohol rehabilitation programs to the chronic alcoholic. These programs are composed primarily of coordianted educational and psychotherapeutic services provided on a group basis. Depending on the subject matter, a series of lectures, discussions, films, and group therapy sessions are led by either physicians, psychologists, or alcoholism counselors from the hospital or various outside organizations. In addition, individual psychotherapy and family counseling (see § 35–14) may be provided in selected cases. These programs are conducted under the supervision and direction of a physician. Patients may directly enter an inpatient hospital rehabilitation program after having undergone detoxification in the same hospital or in another hospital or may enter an inpatient hospital rehabilitation program without prior hospitalization for detoxification.

Alcohol rehabilitation can be provided in a variety of settings other than the hospital setting. In order for an inpatient hospital stay for alcohol rehabilitation to be covered under Medicare it must be medically necessary for the care to be provided in the inpatient hospital setting rather than in a less costly facility or on an outpatient basis. Inpatient hospital care for receipt of an alcohol rehabilitation program would generally be medically necessary where either (1) there is documentation by the physician that recent alcohol rehabilitation services in a less intensive setting or on an outpatient basis have proven unsuccessful and, as a consequence, the

patient requires the supervision and intensity of services which can only be found in the controlled environment of the hospital, *or* (2) only the hospital environment can assure the medical management or control of the patient's concomitant conditions during the course of alcohol rehabilitation. (However, a patient's concomitant condition may make the use of certain alcohol treatment modalities medically inappropriate.) In addition, the "active treatment" criteria (see HCFA–Pub. 13–3, § 3102.1 or HCFA–Pub. 10, § 212.1) should be applied to psychiatric care in the general hospital as well as to psychiatric care in a psychiatric hospital. Since alcoholism is classifiable as a psychiatric condition the "active treatment" criteria must also be met in order for alcohol rehabilitation services to be covered under Medicare. (Thus, it is the combined need for "active treatment" and for covered care *which can only be provided in the inpatient hospital setting*, rather than the fact that rehabilitation immediately follows a period of detoxification, which provides the basis for coverage of inpatient hospital alcohol rehabilitation programs.)

Generally 16–19 days of rehabilitation services are sufficient to bring a patient to a point where care could be continued in other than an inpatient hospital setting. An inpatient hospital stay for alcohol rehabilitation may be extended beyond this limit in an individual case where a longer period of alcohol rehabilitation is medically necessary. In such cases, however, there should be documentation by a physician which substantiates the need for such care. Where the rehabilitation needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by section 1862(a)(1) of the law.

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

C. *Combined Alcohol Detoxification/Rehabilitation Programs.*—Fiscal intermediaries should apply the guidelines in A. and B. above to both phases of a combined inpatient hospital alcohol detoxification/rehabilitation program. Not all patients who require the inpatient hospital setting for detoxification also need the inpatient hospital setting for rehabilitation. (See § 35–22.1 for coverage of outpatient hospital alcohol rehabilitation services.) Where the inpatient hospital setting is medically necessary for both alcohol detoxification and rehabilitation, generally a 3-week period is reasonable and necessary to bring the patient to the point where care can be continued in other than an inpatient hospital setting.

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

35–22.1 OUTPATIENT HOSPITAL SERVICES FOR TREATMENT OF ALCOHOLISM

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

Coverage is available for both diagnostic and therapeutic services furnished for the treatment of alcoholism by the hospital to outpatients subject to the same rules applicable to outpatient hospital services in general (see HCFA–Pub. 13–3, §§ 3312 ff.; HCFA–Pub. 10, §§ 230 ff.). While there is no coverage for day hospitalization programs, per se, individual services which meet the requirements in HCFA–Pub. 13–3, §§ 3112 ff. or HCFA–Pub. 10, §§ 230 ff. may be covered. (Meals, transportation and recreational and social activities do not fall within the scope of covered outpatient hospital services under Medicare.)

All services must be reasonable and necessary for diagnosis or treatment of the patient's condition (see HCFA–Pub. 13–3, § 3151, HCFA–Pub. 10, § 260.1). Thus, educational services and family counseling would only be covered where they are directly related to treatment of the patient's condition. (See also § 35–14.) The frequency of treatment and period of time over which it occurs must also be reasonable and necessary.

35–22.2 TREATMENT OF DRUG ABUSE (CHEMICAL DEPENDENCY)

We recognize that there are similarities between the approach to treatment of drug abuse and alcohol detoxification and rehabilitation. However, the intensity and duration of treatment for drug abuse may vary (depending on the particular substance(s) of abuse, duration of use, and the patient's medical and emotional condition) from the duration of treatment or intensity needed to treat alcoholism. Accordingly, when it is medically necessary for a patient to receive detoxification and/or rehabilitation for drug substance abuse as a hospital inpatient, coverage for care in that setting is available. Coverage is also available for treatment services that are provided in the outpatient department of a hospital to patients who, for example, have been discharged from an inpatient stay for the treatment of drug substance abuse or who require treatment but do not require the availability and intensity of services found only in the inpatient hospital setting. The coverage available for these services is subject to the same rules generally applicable to the coverage of outpatient hospital services. (See HCFA–Pub. 13–3, §§ 3112 ff.; HCFA–Pub. 10, §§ 230 ff.). The services must also be reasonable and necessary for treatment of the individual's condition. (See HCFA–Pub. 13–3, § 3151; HIM–10, § 260.1.) Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by intermediaries based on accepted medical practice with the advice of their

medical consultant. (In hospitals under PSRO review, PSRO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

35–22.3 TREATMENT OF ALCOHOLISM AND DRUG ABUSE IN A FREESTANDING CLINIC

Coverage is available for alcoholism or drug abuse treatment services (such as drug therapy, psychotherapy, and patient education) that are provided incident to a physician's professional service in a freestanding clinic to patients who, for example, have been discharged from an inpatient hospital stay for the treatment of alcoholism or drug abuse or to individuals who are not in the acute stages of alcoholism or drug abuse but require treatment. The coverage available for these services is subject to the same rules generally applicable to the coverage of clinic services. (See HCFA–Pub. 14–3, §§ 2020 ff., and §§ 2050 ff.) Of course, the services also must be reasonable and necessary for the diagnosis or treatment of the individual's alcoholism or drug abuse. The Part B psychiatric limitation (see HCFA–Pub. 14–3, § 2470) would apply to alcoholism or drug abuse treatment services furnished by physicians to individuals who are not hospital inpatients.

35–23 CHEMICAL AVERSION THERAPY FOR TREATMENT OF ALCOHOLISM

Chemical aversion therapy is a behavior modification technique that is used in the treatment of alcoholism. Chemical aversion therapy facilitates alcohol abstinence through the development of conditioned aversions to the taste, smell, and sight of alcohol beverages. This is accomplished by repeatedly pairing alcohol with unpleasant symptoms (e.g., nausea) which have been induced by one of several chemical agents. While a number of drugs have been employed in chemical aversion therapy, the three most commonly used are emetine, apomorphine, and lithium. None of the drugs being used, however, have yet been approved by the Food and Drug Administration specifically for use in chemical aversion therapy for alcoholism. Accordingly, when these drugs are being employed in conjunction with this therapy, patients undergoing this treament need to be kept under medical observation.

Available evidence indicates that chemical aversion therapy may be an effective component of certain alcoholism treatment programs, particularly as part of multimodality treatment programs which include other behavioral techniques and therapies, such as psychotherapy. Based on this evidence, HCFA's medical consultants have recommended that chemical aversion therapy be covered under Medicare. However, since chemical aversion therapy is a demanding therapy which may not be appropriate for all Medicare beneficiaries needing treatment for alcoholism, a physician should certify to the appropriateness of chemical aversion therapy in the individual case. Therefore, if chemical aversion therapy for treatment of alcoholism is determined to be reasonable and necessary for an individual patient, it is covered under Medicare.

When it is medically necessary for a patient to receive chemical aversion therapy as a hospital inpatient, coverage for care in that setting is available. (See § 35–22 regarding coverage of multimodality treatment programs.) Followup treatments for chemical aversion therapy can generally be provided on an outpatient basis. Thus, where a patient is admitted as an inpatient for receipt of chemical aversion therapy, there must be documentation by the physician of the need in the individual case for the inpatient hospital admission.

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

35–23.1 ELECTRICAL AVERSION THERAPY FOR TREATMENT OF ALCOHOLISM (ELECTROVERSION THERAPY, ELECTRO-SHOCK THERAPY, NOXIOUS FARADIC STIMULATION)

Electrical aversion therapy is a behavior modification technique to foster abstinence from ingestion of alcoholic beverages by developing in a patient conditioned aversions to their taste, smell and sight through electric stimulation. Electrical aversion therapy has not been shown to be safe and effective and therefore is excluded from coverage. (See also §§ 35–22, 35–23, and 35–27).

35–24 DIAGNOSIS AND TREATMENT OF IMPOTENCE

Program payment may be made for diagnosis and treatment of sexual impotence. Impotence is a failure of a body part for which the diagnosis, and frequently the treatment, require medical expertise. Depending on the cause of the condition, treatment may be surgical; e.g., implantation of a penile prosthesis, or nonsurgical; e.g., medical or psychotherapeutic treatment. Since causes and, therefore, appropriate treatment vary, if abuse is suspected it may be necessary to request documentation of appropriateness in individual cases. If treatment is furnished to patients (other than hospital inpatients) in connection with a mental condition, apply the psychiatric service limitation described in HCFA Pub. 14–3, § 2470.

35–25 CARDIAC REHABILITATION PROGRAMS.

A. *General.*—Exercise programs for cardiac patients, commonly referred to as cardiac rehabilitation programs, are increasingly being conducted in specialized, free-standing, cardiac rehabilitation clinics as well as in outpatient hospital departments. Exercise programs include specific types of exercise, individually prescribed for each patient.

Medicare coverage of cardiac rehabilitation programs would be considered reasonable and necessary only for patients with a clear medical need, who are referred by their attending physician and (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have had coronary bypass surgery; and/or (3) have stable angina pectoris.

Cardiac rehabilitation programs may be provided either by the outpatient department of a hospital or in a physician-directed clinic. Coverage for either program would be subject to the following conditions:

1. the facility meets the definition of a hospital outpatient department or a physician-directed clinic, i.e., a physician is on the premises available to perform medical duties at all times the facility is open, and each patient is under the care of a hospital or clinic physician;

2. the facility has available for immediate use all the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen,

cardiopulmonary resuscitation equipment, defibrillator, etc;

3. the program is conducted in an area set aside for the exclusive use of the program while it is in session;

4. the program is staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. Services of nonphysician personnel must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise program area and immediately available for an emergency at all times the exercise program is conducted;

5. the nonphysician personnel are employees of either the physician, hospital, or clinic conducting the program and their services are "incident-to a physician's professional services."

Contractors need not undertake elaborate or costly monitoring activities to determine whether these requirements are met, but need only satisfy themselves to the extent that they ordinarily do in connection with, for example, the requirements for coverage of services in physician-directed clinics (see HCFA Pub. 14–3, § 2050.4; HCFA Pub. 13.3, § 3112.4A; HCFA Pub. 10, § 230.4).

In addition to the conditions listed above, coverage for cardiac rehabilitation programs furnished by hospitals to outpatients would also be subject to the rules described in HCFA Pub. 13–3, § 3112.4 and HCFA Pub. 10, § 230.4. Reasonable charge reimbursement for these services which are performed in "freestanding" clinics would be subject to the limitations set forth in HCFA Pub. 14–3, § 5241.

B. *Diagnostic Testing.—Stress Testing.* A prospective candidate for a cardiac rehabilitation program must be evaluated for his suitability to participate. A valuable diagnostic test for this purpose is the stress test. The program need not necessarily perform the stress test, but may accept one performed by the patient's attending physician. Stress testing performed in the outpatient department of a hospital or in a physician-directed clinic may be covered when reasonable and necessary for:

1. evaluation of chest pain, especially atypical chest pain;

2. development of exercise prescriptions for patients with known cardiac disease;

3. pre and postoperative evaluation of patients undergoing coronary artery bypass procedures.

Refer to Section E, Utilization Screens, for the acceptable frequency of stress testing performed during an individual's exercise program.

ECG Rhythm Strips. ECG rhythm strips (and other ECG monitoring) constitute an important and necessary procedure which should be done perodically while a cardiac patient is engaged in a physician-controlled exercise program. See Section E, Utilization Screens, for allowable screens.

C. *Other Diagnostic and Therapeutic Services.*—A freestanding or hospital based cardiac rehabilitation clinic may also provide diagnostic and theraputic services other than stress testing and ECG monitoring. Any such other services must meet the usual coverage requirements for the specific service, e.g., the incident-to, and reasonable and necessary requirements.

1. *Psychotherapy and Psychological Testing.*—It would not normally be considered reasonable and necessary to provide psychotherapy to all cardiac rehabilitation patients, or even to test all such patients to determine whether they may have a mental, psychoneurotic, or personality disorder. However, where a patient has a diagnosed mental, psychoneurotic, or personality disorder, psychotherapy furnished by a psychiatrist—or by a psychologist rendering such services incident to a physician's professional service—may be covered. Similarly, diagnostic testing of a cardiac rehabilitation patient for a mental problem may be covered where the patient shows appropriate symptoms, e.g., excessive anxiety or fear associated with the cardiac disease.

2. *Physical and Occupational Therapy.*—Physical therapy and occupational therapy would not be covered when furnished in connection with cardiac rehabilitation exercise program services covered under this section unless there also is a diagnosed noncardiac condition requiring such therapy, e.g., where a patient who is just recuperating from an acute phase of heart disease may have had a stroke which would require physical and/or occupational therapy. (While the cardiac rehabilitation exercise program may by some be considered a form of physical therapy, it is a specialized program conducted and/or supervised by specially trained personnel whose services are performed under the direct supervision of a physician.) Restrictions on coverage of physical therapy and occupational therapy under this section do not affect rules regarding coverage or noncoverage of such services when furnished in a hospital inpatient or outpatient setting.

(See HCFA Pub. 13–3, § 3101.9 and HCFA Pub. 10, § 210.9.)

3. *Patient Education Services.*—Many cardiac rehabilitation programs provide health education in the form of lectures or counseling in which patients and/or family members are given information, e.g., on diet, nutrition, and sexual activity to assist them in adjusting their living habits because of the cardiac condition. However, the same kind of information would have been furnished to a patient and/or family members by the attending physician following the patient's acute cardiac episode. Therefore, formal lectures and couseling on these subjects would not be considered reasonable and necessary as a separately identifiable service when provided as part of a cardiac rehabilitation exercise program. In addition, where a free-standing cardiac rehabilitation clinic provides board and room for the patient (and in some cases family members), these services would not be covered under Medicare.

D. *Duration of the Program.*—Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions, usually 3 sessions a week in a single 12 week period. Coverage for continued participation in cardiac exercise programs beyond 12 weeks would be allowed only on a case-by-case basis with exit criteria taken into consideration.

Although firm exit criteria for terminating the therapeutic outpatient exercise treatment and rehabilitation program have not been established, the following guidelines have been identified as acceptable when the patient progresses to a maintenance program:

1. The patient has achieved a stable level of exercise tolerance without ischemia or dysrhythmia.

2. Symptoms of angina or dyspnea are stable at the patient's maximum exercise level.

3. Patient's *resting* blood pressure and heart rate are within normal limits.

4. The stress test is not *positive* during exercise. (A *positive test* in this context implies an ECG with a junctional depression of 2mm or more associated with slowly rising, horizontal, or down sloping ST segment.)

Accordingly, claims for coverage of cardiac rehabilitation exercise programs beyond 12 weeks should be reviewed by contractors' medical consultants. When claims are accompanied by acceptable documentation that the patient has not reached an exit level, coverage may be extended, but should not exceed a maximum of 24 weeks.

E. *Utilization Screens.*—Patients who participate in cardiac rehabilitation programs will require certain services more frequently than other patients being treated on an outpatient basis. Therefore, in order to provide coverage in a uniform manner, the following utilization screens should be implemented in addition to existing screens for any cardiac rehabilitation services not listed:

1. *Group 1 Services*

a. Continuous ECG telemetric monitoring during exercise.

b. ECG rhythm strip with interpretation and physician's revisions of exercise prescription.

c. Limited examination for physician followup to adjust medication or other treatment changes.

A visit including one or more of this range of routine services would be considered as one routine cardiac rehabilitation visit. In order for the visit to be reimbursable, at least one of the Group 1 services must be performed. The same rate of reimbursement would be allowed for each visit, but not all the services need be performed at each visit.

Allow a maximum of three visits per week.

2. *Group 2 Services*

a. New patient comprehensive evaluation, including history physical, and preparation of initial exercise prescription.

Allow one at the beginning of the program if not already performed by the patient's attending physician, or if that performed by the patient's attending physician is not accpetable to the program's director.

b. ECG stress test (treadmill or bicycle ergometer) with physician monitoring and report.

Allow one at the beginning of the program and one after 3 months (usually the completion of the program).

c. Other physician services, as needed.

35–26 TREATMENT OF OBESITY

Obesity itself cannot be considered an illness. The immediate cause is a caloric intake which is persistently higher than caloric output. Program payment may not be made for treatment for obesity alone since this treatment cannot be considered reasonable and necessary for the diagnosis or treatment of an illness or injury. However, although obesity is not in itself an illness, it may be caused by illnesses such as hypothyroidism, Cushing's disease, and hypothalamic lesions. In addition, obesity can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Therefore, services in connection with the treatment of obesity could be covered services when such services are an integral and necessary part of a course of treatment for one of these illnesses.

Cross refer: CIA 35–33 and 35–40.

35–26.1 SUPPLEMENTED FASTING

Supplemented fasting is a type of very low calorie weight reduction regiment used to achieve rapid weight loss. The reduced calorie intake is supplemented by a mixture of protein, carbohydrates, vitamins and minerals. Serious questions exist about the safety of prolonged adherence for 2 months or more to a very low calorie weight reduction regimen as a general treatment for obesity, because of instances of cardiopathology and sudden death, as well as possible loss of body protein. Therefore, supplemented fasting is not covered as a general treatment for obesity.

In cases where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient may be covered under Medicare on a case-by-case basis, as determined by the contractor's medical consultant. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

35–27 BIOFEEDBACK THERAPY

Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured.

Biofeedback therapy differs from electromyography, which is a diagnostic procedure used to record and study the electrical properties of skeletal muscle. An electromyography device may be used to provide feedback with certain types of biofeedback, however.

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions. (See HCFA–Pub. 14–3, §§ 2200ff, 2215, and 4161; HCFA–Pub. 13–3, §§ 3133.3, 3148, and 3149; HCFA–Pub. 10, §§ 242 and 242.5 for special physical therapy requirements. See also 35–20 and 65–8.)

35–29 OXYGEN TREATMENT OF INNER EAR/CARBON THERAPY

(Effective for services performed on and after August 1, 1978).—Not covered.

Oxygen (95 percent) and carbon dioxide (5 percent) inhalation therapy for inner ear disease, such as endolymphatic hydrops and fluctuant hearing loss, cannot be considered reasonable and necessary. The therapeutic benefit deriving from this procedure is highly questionable.

35–30 BLOOD PLATELET TRANSFUSIONS AND BONE MARROW TRANSPLANTATION

A. *Blood Platelet Transfusions.*

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

Blood platelet transplants are safe and effective for the correction of thrombocytopenia and other blood defects. If such treatment is reasonable and necessry for the individual patient, it is covered under Medicare.

B. *Allogeneic Bone Marrow Transplantation.*

Allogeneic bone marrow transplantation is a procedure in which a portion of a healthy donor's bone marrow is obtained and prepared for intravenous infusion to restore normal marrow function in recipients having an inherited or acquired marrow deficiency or defect.

THE FOLLOWING USES OF ALLOGENEIC BONE MARROW TRANSPLANTATION ARE COVERED UNDER MEDICARE:

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

1. For the treatment of leukemia or aplastic anemia when it is reasonable and necessary for the individual patient to receive this therapy.

(Effective for services performed on or after June 3, 1985.)

2. For the treatment of severe combined immunodeficiency disease (SCID).

3. For the treatment of Wiskott-Aldrich syndrome.

C. *Autologous Bone Marow Transplantation.*

(Effective for services performed on or after *04/28/89.*)

Autologores bone marrow transplantation is a technique for restoring bone marrow stem cells using the patient's own previously stored marrow.

1. *Covered Conditions.*—Autologous bone marrow transplantation (ICD–9–CM code 41.01, CPT–4 code 38240) is considered reasonable and necessary under § 1862(a)(1) of the Medicare law for the following conditions and is covered under Medicare for patients with:

- Acute leukemia in remission (ICD–9–CM code NEC V 10.60) who have a high probability of relapse and who have no HLA—matched donor (codes lymphoid V10.61, monocytic V10.63, myeloid V 10.62, NEC V10.69);
- Resistant non-Hodgkin's lymphomas (ICD–9CM codes 202.80–202.88) or those presenting with poor prognostic features following an initial response;
- Recurrent or refractory neuroblastoma (see ICD–9CM Neoplasm by site, malignant); or
- Advanced Hodgkin's disease (ICD–9CM code 201) who have failed conventional therapy and have no HLA-matched donor.

2. *Noncovered Conditions.*—Insufficient data exist to establish definite conclusions regarding the efficacy of autologous bone marrow transplantation for the following conditions:

- Acute leukemia in relapse (ICD–9CM codes 204.0, 205.0, 206.0, and 208.0);
- Chronic granulocytic leukemia (ICD–9CM code 205.1); or
- Solid tumors (other than neuroblastoma) (ICD–9CM codes 140–199).

In these cases, autologous bone marrow transplantation is not considered reasonable and necessary within the meaning of § 1862(a)(1) of the Medicare law and is not covered under Medicare for these conditions.

35–31 TREATMENT OF DECUBITUS ULCERS

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

35–32 VERTEBRAL ARTERY SURGERY

Obstructions which block the flow of blood through the vertebral artery can cause vertigo, visual or speech defects, ataxia, mental confusion, or stroke. These symptoms in patients result from reduction in blood flow to the brain and range from symptoms of transient basilar ischemia to mental deterioration or completed stroke.

Five types of surgical procedures are performed to relieve obstructions to vertebral artery blood flow. They are:

1. Vertebral artery endarterectomy, a procedure which cleans out arteriosclerotic plaques which are inside the vertebral artery;
2. Vertebral artery by-pass or resection with anastomosis or graft;
3. Subclavian artery resection with or without endarterectomy;
4. Removal of laterally located osteophytes anywhere in the $C_6(C_7)$–C_2 course of the vertebral artery; and
5. Arteriolysis which frees the artery from surrounding tissue, with or without arteriopexy (fixation of the vessel).

These procedures can be medically reasonable and necessary, but only if each of the following conditions is met:

1. Symptoms of vertebral artery obstruction exist;
2. Other causes have been considered and ruled out;
3. There is radiographic evidence of a valid vertebral artery obstruction; and
4. Contraindications to the procedure do not exist, such as coexistent obstructions of multiple cerebral vessels.

Angiograms documenting a valid obstruction should show not only the aortic arch with the vessels off the arch, but also show the vessels in the neck and head (providing biplane views of the carotid and vertebral vascular system). In addition, serial views are needed to diagnose "subclavian steal," the condition in which subclavian artery obstruction causes the symptoms of vertebral artery obstruction. Because the symptoms are not specific for vertebral artery obstruction, other causes must be considered. In addition to vertebral artery obstruction, the differential diagnosis should include various degenerative disorders of the brain, orthostatic hypotension, acoustic neuroma, labyrinthitis, diabetes mellitus and hypoglycemia related disorders.

Obstructions which can cause symptoms of blocked vertebral artery blood flow and which can be documented by an angiogram include:

1. Intravascular obstructions—arteriosclerotic lesions within the vertebral artery or in the other arteries.
2. Extravascular obstructions—

a. Bony tissue or osteophytes, located laterally in the $C_6(C_7)$–C_2 cervical vertebral area course of the vertebral artery, most commonly at C_5–C_6.

b. Anatomical variations—Anomalous location of the origin of the vertebral artery, a congenital aberration, and tortuosity and kinks of the vertebral artery.

c. "Fiberous tissue"—Tissue changed as a result of manipulation of the neck for neck pain or injury associated with hematoma; "external bands," "tendinous slings," and "fibrous bands."

The most controversial obstructions include vertebral artery tortuosity and kinks and connective tissue along the course of the vertebral artery, and variously called "external bands," "tendinous slings" and "fibrous bands." In the absence of symptoms of vertebral artery obstruction, vascular surgeons feel such abnormalities are insignificant. Vascular surgery experts, however, agree that these abnormalities in very rare cases do cause symptoms of vertebral artery obstruction and do necessitate surgical correction.

"Vertebral artery construction" and "vertebral artery surgery" are phrases which most physicians interpret to include only surgical cleaning (endarterectomy) and bypass (resection) procedures. However, some physicians who use these terms mean all operative manipulations which remove vertebral artery blood flow obstructions. Also, some physicians use general terms of vascular surgery, such as "endarterectomy" when vertebral artery related surgery is performed. Use of the above terminology specifies neither the surgical procedure performed nor its relationship to the vertebral artery. Therefore, in developing claims for this type of procedure, the Medicare contractors should require specific identification of the obstruction in question and the surgical procedure performed. Also, in view of the specific coverage criteria given above, the Medicare contractors are expected to develop all claims for vertebral artery surgery on a case-by-case basis.

Payment may be made for a surgical procedure listed above if: (1) It is reasonable and necessary for the

individual patient to have the surgery performed to remove or relieve an obstruction to vertebral artery flow, and (2) The four conditions noted above are met.

In all other cases, these procedures cannot be considered reasonable and necessary within the meaning of § 1862(a)(1) of the Medicare law and are not reimbursable under the program.

35–33 INTESTINAL BY-PASS SURGERY—NOT COVERED

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

Cross-refer: §§ 35–26, 35–40.

35–34 FABRIC WRAPPING OF ABDOMINAL ANEURYSMS—NOT COVERED

Fabric wrapping of abdominal aneurysms is not a covered Medicare procedure. This is a treatment for abdominal aneurysms which involves aneurysms with cellophane or facia lata. This procedure has not been shown to prevent eventual rupture. In extremely rare instances, external wall reinforcement may be indicated when the current accepted treatment (excison of the aneurysm and reconstruction with synthetic materials) is not a viable alternative, but external wall reinforcement is not "fabric wrapping". Accordingly, fabric wrapping of abdominal aneurysms is not considered reasonable and necessary within the meaning of § 1862(a)(1) of the law.

35–35 THERAPEUTIC EMOBOLIZATION (EFFECTIVE FOR SERVICES PERFORMED ON OR AFTER APRIL 15, 1982)

Theurapeutic embolization is covered when done for hemorrhage, and for other conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient. Renal emoblization for the treatment of renal adenocarcinoma continues to be covered, effective December 15, 1978, as one type of therapeutic emoblization, to:

- Reduce tumor vascularity preoperatively;
- Reduce tumor buld in inoperable cases; or
- Palliate specific symptoms.

35–37 EXTRAINTRACRANIAL ARTERY BYPASS (EIAB) SURGERY IN THE TREATMENT OF STROKES (EFFECTIVE FOR SERVICES FURNISHED ON OR AFTER SEPTEMBER 1, 1979)

Extraintracranial artery bypass (EIAB) surgery is covered for the following indications:

1. Occlusion or stenosis of the inaccessible portion of the internal carotid artery presenting with a transient ischemic attack (TIA), prolonged reversible ischemic neurological deficit (PRIND), or completed stroke (CS).
2. Middle cerebral artery stenosis or occlusion presenting with TIA, PRIND, or CS.
3. A longstanding complete internal carotid occlusion considered inoperable by carotid endarterectomy because of difficulties in establishing or maintaining patency.
4. In prevention of an expected vascular insufficiency in surgical treatment of a giant aneurysm of the carotid bifurcation or middle cerebral artery and of skull based tumors involving internal carotid and middle cerebral artery.

Patients with the following conditions are generally not candidates for EIAB surgery, and payment may be made in those cases only if the intermediary's medical consultants determine that there is sufficient medical justification for the procedure to be performed in the patient's case.

1. Strokes with major severe neurological deficits.
2. Stroke in evolution. There are a small number of such patients with known occlusion of the internal carotid who may benefit by EIAB surgery during the period of evolution.
3. Cerebral edema.
4. Diffuse cerebral occlusive disease.
5. Severe cardiopulmonary disease and other diseases such as diabetes which contribute significantly to the mortality and morbidity of the operation.

35–38 ULTRAFILTRATION, HEMOPERFUSION AND HEMOFILTRATION

A. *Ultrafiltration.*—is a process for removing excess fluid from the blood through the dialysis membrane by means of pressure. It is not a substitute for dialysis. Ultrafiltration is utilized in cases where excess fluid cannot be removed easily during the regular course of hemodialysis. When it is performed it is commonly done during the first hour or two of each hemodialysis on patients who, e.g., have refractory edema. Ultrafiltration is a covered procedure under the Medicare program (effective for services performed on and after 9/1/79).

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

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

B. *Hemoperfusion.*—A process which removes substances from the blood using a charcoal or resin artifical kidney. When used in the treatment of life threatening *drug overdose,* hemoperfusion is a covered service for patients with or without renal failure (effective for services performed on and after 9/1/79). Hemoperfusion generally requires a physician to be present to initiate treatment and to be present in the hospital or an adjacent medical office during the entire procedure, as changes may be sudden. Special staff training and equipment are required.

Develop charges for hemoperfusion in the same manner as for any new or unusual service. One or two treatments are usually all that is necessary to remove the toxic compound; document additional treatments. Hemoperfusion may be performed concurrently with dialysis, and in those cases payment for the hemoperfusion reflects only the additional care rendered over and above the care which is given to the dialysis.

The effects of using hemoperfusion to *improve* the results of *chronic hemodialysis* are not known. Therefore, hemoperfusion is not a covered service when used to improve the results of hemodialysis. In addition, it has not been demonstrated that the use of hemoperfusion in conjunction with DFO, in treating symptomatic patients with

iron overload, is efficacious. There is also a paucity of data regarding its efficacy in treating asymptomatic patients with iron overload. Therefore, hemoperfusion used in conjunction with DFO in treating patients with iron overload is not a covered service; i.e., it is not considered reasonable and necessary within the meaning of § 1862(a)(1) of the law.

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

C. *Hemofiltration.*—A process which removes fluid, electrolytes and other low molecular weight toxic substances from the blood by filtration through hollow artificial membranes and may be routinely performed in 3 weekly sessions. Hemofiltration (which is also known as diafiltration) is a covered procedure under Medicare and is a safe and effective technique for the treatment of ESRD patients and an alternative to pertioneal dialysis and hemodialysis (effective for services performed on and after August 20, 1987). In contrast to both hemodialysis and pertioneal dialysis treatments, which eliminate dissolved substances via diffusion across semipermeable membranes, hemofiltration mimics the filtration process of the normal kidney. The technique requires an arteriovenous access. Hemofiltration may be performed either in facility or at home.

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

Cross-refer: Intermediary Manual, § 3188

35–39 INTRAOCULAR PHOTOGRAPHY (EFFECTIVE FOR SERVICES FURNISHED ON OR AFTER SEPTEMBER 1, 1979)

Intraocular photography may be covered when used for the diagnosis of such conditions as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, or to identify glaucoma, multiple sclerosis and other central nervous system abnormalities. Medicare payment may be made for the use of this procedure by an opthalmologist in these situations when it is reasonable and necessary for the individual patient to receive these services.

35–40 GASTRIC BYPASS SURGERY FOR OBESITY (EFFECTIVE FOR SERVICES PERFORMED ON AND AFTER OCTOBER 1, 1979)

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

Cross-refer: §§ 35–26, 35–33.

35–41 DIATHERMY AND DIAPULSE TREATMENT

Since Diapulse, Theramatic (standard model only), Spectrowave and Superpulse are not able to sufficiently elevate tissue temperature to produce a therapeutic effect, reimbursement for treatment utilizing such low energy pulsed wave diathermy devices is not appropriate. However, other pulsed wave diathermy machines have been found to produce some degree of therapeutic benefit for essentially the same conditions and to the same extent as standard diathermy. Accordingly, where the contractor's medical staff has determined that the pulsed wave diathermy apparatus used is one which is considered therapeutically effective, the treatments are considered a covered service, but only for those conditions for which standard diathermy is medically indicated and only when rendered by a physician or incident to a physician's professional services. Further, when the charge for covered pulsed wave diathermy treatment is substantially in excess of that which is reasonable for standard diathermy, reimbursement is based on the reasonable charge for standard diathermy.

Cross-refer: §35–3.

35–42 WITHDRAWAL TREATMENTS FOR NARCOTIC ADDICTIONS

Withdrawal is an accepted treatment for narcotic addiction, and Part B reimbursement can be made for these services if they are provided by the physician directly or under his personal sueprvision and if they are reasonable and necessary. In reviewing claims, reasonableness and necessity are determined with the aid of the contractor's medical staff.

Drugs that the physician provides in connection with this treatment are also covered if they cannot be self-administered and meet all other statutory requirements.

Cross-refer: Intermediary Manual, § 3112.4B; Carriers Manual, § 2050.5.

35–44 GENERAL ANESTHESIA IN CATARACT SURGERY

A. *Pre-Surgery Evaluations.*—(Effective for services performed on or after *09–14–88.*) Cataract surgery with an intraocular lens (IOL) implant is a high volume Medicare procedure. Along with the surgery, a substantial number of preoperative tests are available to the surgeon. In most cases, a comprehensive eye examination (ocular history and ocular examination) and a single scan to determine the appropriate pseudophakic power of the IOL are sufficient. In most cases involving a simple cataract, a diagnostic ultrasound A-scan is used. For patients with a dense cataract, an ultrasound B–scan may be used.

Accordingly, where the only diagnosis is "cataract(s)," Medicare will not routinely cover testing other than one comprehensive eye examination (or a combination of a brief/intermediate examination not to exceed the charge of a comprehensive examination) and an A-scan or, if medically justified, a B-scan. Claims for additional tests will be denied as not reasonable and necessary unless there is an additional diagnosis *and* the medical need for the additional test is fully documented.

Because cataract surgery is an elective procedure, the patient may decide not to have the surgery until later, or to have the surgery performed by a physician other than the diagnosing physician. In these situations, it may be medically appropriate for the operating physician to conduct another examination. To the extent the additional tests are considered reasonable and necessary by the carrier's medical staff, they would be covered.

B. *General Anesthesia.*—The use of general anesthesia in cataract surgery may be considered reasonable and necessary if, for particular medical indications, it is the accepted procedure among opthalmologists in the local community to use general anesthesia. In the claims review process, do not "front-end" reject any claims for the use of general anesthesia in cataract surgery. Obtain advice from your medical consultants before deciding whether to deny a claim involving use of general anesthesia in cataract surgery. Where regular postpayment review discloses a questionable utilization pattern, obtain case documentation.

35–45 CARDIAC CATHETERIZATION PERFORMED IN OTHER THAN A HOSPITAL SETTING. (EFFECTIVE FOR SERVICES PERFORMED ON OR AFTER 07/01/79.)

Cardiac catheterization performed in a hospital setting for either inpatients or outpatients is a covered service. The procedure may also be covered when performed in a freestanding clinic when the carrier, in consultation with the appropriate Peer Review Organization (PRO), determines that the procedure can be performed safely in all respects in the particular facility. Prior to approving Medicare reimbursement for cardiac catheterizations performed in freestanding clinics, *carriers must request PRO review* of the clinic.

35–46 ASSESSING PATIENT'S SUITABILITY FOR ELECTRICAL NERVE STIMULATION THERAPY.

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

A. *Transcutaneous Electrical Nerve Stimulation (TENS).*—This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See § 45–25 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain, electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain. (See § 35–46B.)

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

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

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

Note.—Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his physician, physical therapist or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his home. Electrical nerve stimulation treatments furnished by a physician in his office, by a physical therapist or outpatient clinic are excluded from coverage by § 1862(a)(1) of the law. (See § 65–8 for an explanation of coverage of the therapeutic use of transcutaneous and implanted peripheral nerve stimulators under the prosthetic devices benefit.)

35–47 BREAST RECONSTRUCTION FOLLOWING MASTECTOMY—(EFFECTIVE FOR SERVICES PERFORMED ON AND AFTER MAY 15, 1980)

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

- a change in epidemiology of breast cancer, include an apparent increase in incidences;
- improved surgical skills and techniques;
- the continuing development of better prostheses; and
- increasing awareness by physicians of the importance of postsurgical psychological adjustment. Breast reconstruction following mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for this procedure.

35–48 OSTEOGENIC STIMULATION—(EFFECTIVE FOR SERVICES PERFORMED ON AND AFTER SEPTEMBER 15, 1980)

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

Use of the noninvasive stimulator is covered for the following indications:

- Nonunion of long bone fractures;
- Failed fusion; and
- Congenital Pseudarthroses

Use of the invasive device is covered only for nonunion of long bone fractures.

Nonunion, for all types of devices, is considered to exist only after six or more months have elapsed without healing of the fracture.

35–49 HYPERTHERMIA FOR TREATMENT OF CANCER (EFFECTIVE FOR SERVICES PERFORMED ON OR AFTER 12/31/84.)

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

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

35–50 COCHLEOSTOMY WITH NEUROVASCULAR TRANSPLANT FOR MENIERE'S DISEASE—NOT COVERED

Meniere's disease (or syndrome) is a common cause of paroxysmal vertigo. Meniere's syndrome is usually treated medically. When medical treatment fails, surgical treatment may be required.

While there are two recognized surgical procedures used in treating Meniere's disease (decompression of the endolymphatic hydrops and labyrnthectomy), there is no scientific evidence supporting the safety and effectiveness of cochleostomy with neurovascular transplant in treatment of Meniere's syndrome. Accordingly, Medicare does not cover cochleostomy with neurovascular transplant for treatment of Meniere's disease.

35–51 HEMODIALYSIS FOR TREATMENT OF SCHIZOPHRENIA—NOT COVERED

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

35–52 LASER PROCEDURES

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

35–53 LIVER TRANSPLANTATION—LIMITED COVERAGE

For most people, liver transplantation is considered an experimental procedure and, therefore, is not covered. However, effective for services rendered on or after February 9, 1984, liver transplantation is no longer considered experimental with respect to children (under age 18) withr extrahepatic biliary atresia or any other form of end-stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia, since existing data indicate that the potential for benefit from liver transplantation in this group is low. Children's claims for liver transplantation should be developed for medical necessity on an individual case basis.

35–54 REFRACTIVE KERATOPLASTY—NOT COVERED

Refractive keratoplasty is surgery to reshape the cornea of the eye to correct vision problems such as myopia (nearsightedness) and hyperopia (farsightedness). Refractive keratoplasty procedures include keratomileusis, in which the front of the cornea is removed, frozen, reshaped, and stitched back on the eye to correct either near or farsightedness; keratophakia, in which a reshaped donor cornea is inserted in the eye to correct farsightedness; and radial keratotomy, in which spoke-like slits are cut in the cornea to weaken and flatten the normally curved central portion to correct nearsightedness.

Refractive keratoplasty in any form is not covered because it is still under investigation, and has not yet been subjected to adequate scientific evaluation in humans.

35–55 TRANSVENOUS (CATHETER) PULMONARY EMBOLECTOMY—NOT COVERED

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

35–56 FLUIDIZED THERAPY DRY HEAT FOR CERTAIN MUSCULOSKELETAL DISORDERS

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

35–57 ELECTROENCEPHALOGRAPHIC MONITORING DURING SURGICAL PROCEDURES INVOLVING THE CEREBRAL VASCULATURE

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

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

35–57.1 ELECTROENCEPHALOGRAPHIC (EEG) MONITORING DURING OPEN-HEART SURGERY—NOT COVERED

The value of EEG monitoring during open-heart surgery and in the immediate post-operative period is debatable, because there are little published data based on well-designated studies regarding its clinical effectiveness. The procedure is not frequently used and does not enjoy widespread acceptance of benefit.

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

35–58 THORACIC DUCT DRAINAGE (TDD) IN RENAL TRANSPLANTS

Thoracic Duct Drainage (TDD) is an immunosuppressive technique used in renal transplantation. This procedure, which removes lymph from kidney transplant recipients as a means of achieving suppression of the immune mechanism, is currently being used both pre-transplant and post-transplant, in conjunction with more conventional immunotherapy. TDD is performed on an inpatient basis and the inpatient stay is covered for patients admitted for treatment in advance of a kidney transplant as well as for those receiving it post-transplant.

TDD is a covered technique when furnished to a kidney transplant recipient or an individual approved to receive kidney transplantation by a

hospital approved to perform kidney transplantation.

35–59 ENDOSCOPY

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

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

35–60 THERAPEUTIC PHERESIS (APHERESIS)

Pheresis is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma or cells) from whole blood and return the remaining consituents to the person from whom the blood was taken.

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

Therapuetic pheresis is covered for the following indications:

A. Plasma, exchange for acquired myasthenia gravis.

B. Leukapheresis in the treatment of leukemia.

C. Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom).

D. Apheresis in the treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes.

The following uses of apheresis are covered for services performed on or after January 31, 1983.

E. Plasmapheresis or plasma exchange as a last resort treatment of thrombotic thrombocytopenic purpura (TTP).

F. Plasmapheresis or plasma exchange in the last-resort treatment of life-threatening rheumatoid vasculitis when all other conventional therapies have failed.

The following use of apheresis is covered for services performed on or after October 19, 1983.

G. Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease.

The following uses of apheresis are covered for services performed on or after September 6, 1984.

H. Plasma exchange in the treatment of Goodpasture's Syndrome.

I. Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage.

The following uses of apheresis are covered for services performed on or after October 15, 1984.

J. Apheresis in the treatment of chronic relapsing polyneuropathy for patients with severe or life-threatening symptoms who have failed to respond to conventional therapy.

K. Apheresis in the treatment of life-threatening scleroderma and polymyositis, when the patient is unresponsive to conventional therapy.

The following uses of apheresis are covered for services performed on or after February 14, 1986.

L. Apheresis for the treatment of Guillain-Barre Syndrome.

M. Apheresis as a treatment of last resort for life-threatening Systemic Lupus Erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

Apheresis is covered only when performed in the inpatient or outpatient hospital setting.

35–61 TRANSSEXUAL SURGERY

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses.

Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications of these surgical procedures. For these reasons, transsexual surgery is not covered.

35–62 INVASIVE INTRACRANIAL PRESSURE MONITORING

Invasive intracranial pressure monitoring is a safe and effective therapeutic tool used to monitor intracranial pressure, usually used for patients suffering from head injury, subarachnoid hemorrhage, intracerebral hemorrhage, Reye's syndrome, and posthypoxic, metabolic, and viral encephalopathies. It is usually performed in specialized intensive care units for neurosurgical and neurologic patients. It is a covered procedure when reasonable and necessary for the individual patient.

35–63 TINNITUS MASKING

A tinnitus masker is a device designed to be worn like a behind-the-ear hearing aid by persons seeking relief from tinnitus, which is the perception of noise in the ear and/or head area. The masker produces external sounds to distract the person from the tinnitus.

By producing an external sound a few decibels above the person's audible threshhold, tinnitus masking is thought to provide sufficient distraction from subjective idiopathic tinnitus to alleviate the discomfort and debilitation associated with endogenous sounds within the ear and/or head area.

Tinnitus masking is considered an experimental therapy at this time, because of the lack of controlled clinical trials demonstrating effectiveness, in addition to the unstudied possibility of serious toxicity in the form of noise-induced hearing loss. Therefore, it is not covered.

35–64 CHELATION THERAPY FOR TREATMENT OF ATHEROSCLEROSIS

Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered.

Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than

atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

Cross-refer: § 45–20.

35–65 GASTRIC FREEZING

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

35–66 TREATMENT OF PSORIASIS

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

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

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

35–67 MELODIC INTONATION THERAPY (Effective for Services Performed On or After March 11, 1983)

Melodic intonation therapy is a technique used in language rehabilitation. Its purpose is to teach aphasic patients to produce useful phrases by intoning them in a melodic pattern with strong rhythmic support. Limited studies by a few institutions show some benefit for a small number of nonfluent aphasic patients otherwise unresponsive to conventional therapy.

Melodic intonation therapy is a covered service only for nonfluent aphasic patients unresponsive to conventional therapy, and only when the conditions for coverage of speech pathology services are met. Please refer to HCFA–Pub. 14–3, §§ 2200–2206.4, and 2216, HCFA–Pub. 13–3, §§ 3101.19A, and 3147–3148.4; or HCFA-Pub. 10 §§ 241–242.5 for these conditions of coverage.

35–69 IMPLANTATION OF ANTI-GASTROESOPHAGEAL REFLUX DEVICE.—(Effective for Services Performed On or After 06/22/87.)

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

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

- have esophageal involvement with progressive systemic sclerosis; or
- have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction; or
- are poor surgical risks for a valvuloplasty procedure; or
- have failed previous attempts at surgical treatment with valvuloplasty procedures.

35–70 CLOSED-LOOP BLOOD GLUCOSE CONTROL DEVICE (CBGCD).—(Effective for Services Rendered On or After 7/1/83.)

The closed-loop blood glucose control device (CBGCD) is a hospital bedside device designed for short-term management of patients with insulin dependent diabetes mellitus (Type I). It consists of a rapid on-line glucose analyzer; a computer with a controller for the calculation and control of the infusion of either insulin or dextrose; a multi-channel infusion system; and a printer designed to record continuous glucose values and to provide cumulative totals of the substances infused. Its primary use is for the stabilization of Type I diabetics during periods of stress, such as trauma, labor and delivery, and surgery, when there are wide fluctuations in blood sugar levels. It serves to temporarily correct abnormal blood glucose level (hyper- or hypo-glycemia) and this correction is made by infusion of either insulin or dextrose. Its use is generally limited to a 24- to 48-hour period because of potential complications (e.g., sepsis, thromboses, and nonportability, etc.). The CBGCD requires specialized training for use and interpretation of its diagnostic and therapeutic contribution and continuous observation by specially trained medical personnel.

Use of the CBGCD is covered for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.

35–71 NONSELECTIVE (RANDOM) TRANSFUSIONS AND LIVING—RELATED DONOR SPECIFIC TRANSFUSIONS (DST) IN KIDNEY TRANSPLANTATION.—(Effective for Services Rendered on or After 12/01/83.)

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

These pretransplant transfusions are covered under Medicare without a specific limitation on the number of transfusions, subject to the normal Medicare blood deductible provisions. Where blood is given directly to the transplant patient; e.g., in the case of donor specific transfusions, the blood is considered replaced for purposes of the blood deductible provisions. (See HCFA Pub. 13–3 § 3235.4; HCFA Pub. 14–3 § 2455, and HCFA Pub. 10 §§ 222.3.)

35–72 ELECTROTHERAPY FOR TREATMENT OF FACIAL NERVE PARALYSIS (BELL'S PALSY).—NOT COVERED.

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

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

35–73 INJECTION SCLEROTHERAPY FOR ESOPHAGEAL VARICEAL BLEEDING. (Effective for Services Performed on or After 10/29/84.)

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

35–74 EXTERNAL COUNTERPULSATION (ECP).—NOT COVERED.

External counterpulsation, a noninvasive means of producing the hemodynamic effects of intravascular counterpulsation, is a way of supporting a failing circulatory system due to myocardial infarction and cardiogenic shock by helping the heart pump more blood with less effort. The device uses the patient's legs as a pumbing chamber by enclosing the leg in rigid cylinders with a water-filled bag situated between the patient's legs and the cylinders, and changing the vascular pressure by alternate infusion and removal of water from the bag. An electrocardiogram with delay and duration circuits controls phasing of the pump with cardiac action.

Although the external counterpulsation device appears to be safe, published clinical evidence and the option of the medical community do not support the clinical utility of the device as a means of treating heart failure. While external counterpulsation appears to yield some benefits, there is less evidence that it reduces systolic pressure and, thus, the workload of the heart. External counterpulsation is therefore, not covered under Medicare.

35–75 INTRAOPERATIVE VENTRICULAR MAPPING—(Effective for services rendered on or after 10/29/84.)

Intraoperative ventricular mapping is the technique of recording cardiac electrical activity directly from the heart. The recording sites are usually identified from an anatomical grid and may consist of epicardial, intramural, and endocardial sites. A probe with electrodes is used to explore these surfaces and generate a map that displays the sequence of electrical activation. This information is used by the surgeon to locate precisely the site of an operative intervention.

The intraoperative ventricular mapping procedure is covered under Medicare only for the uses and medical conditions described below:

- localize accessory pathways associated with the Wolff-Parkinson-White (WPW) and other preexcitation syndromes;
- map the sequence of atrial and ventricular activation for drug-resistant supraventricular tachycardias;
- delineate the anatomical course of His bundle and/or bundle branches during corrective cardiac surgery for congenital heart diseases; and
- direct the surgical treatment of patients with refractory ventricular tachyarrhythmias.

35–77 NEUROMUSCULAR ELECTRICAL STIMULATION (NMES) IN THE TREATMENT OF DISUSE ATROPHY (Effective for services performed on and after 11–5–84.)

Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. Coverage of NMES is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse are causing atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). (See § 45–25 for an explanation of coverage of medically necessary supplies for the effective use of NMES.)

35–78 DIAGNOSTIC ENDOCARDIAL ELECTRICAL STIMULATION (PACING)—Effective for services performed on or after 12–03–84.)

Diagnostic endocardial electrical stimulation (EES), also called programmed electrical stimulation of the heart, is covered under Medicare when used for patients with severe cardiac arrhythmias.

Diagnostic endocardial electrical stimulation involves the detection and stimulation of cardiac electrical activity for the purpose of studying arrhythmias and abnormalities of the heart's conduction system. Intracardiac electrode catheters, intracardiac and extracardiac recordings and a stimulator device are required. From two to six multipolar electrode catheters are inserted percutaneously, usually through the femoral veins, and advanced to the heart under fluoroscopic control. Other venous are arterial routes may be employed as well. An intracardiac His bundle cardiogram is usually obtained during EES as are conventional electrocardiograms. No separate charge will be recognized for the His Bundle cardiogram. (See § 50–3.)

EES is used to investigate the mechanisms, site of origin and pathways of cardiac arrhythmias as well as to select therapeutic approaches for their resolution. EES is also employed to identify patients at risk of sudden arrhythmic death. The principal use for EES is in the diagnosis and treatment of sustained ventricular tachycardia. However, it has also proven to be of value in the diagnosis and management of other complex arrhythmias, conduction defects, and after cardiac arrest.

35–79 ANESTHESIA IN CARDIAC PACEMAKER SURGERY (Effective for services performed on or after *July 27, 1988.*

The use of general or monitored anesthesia during *transvenous* cardiac pacemaker surgery may be reasonable and necessary and therefore covered under Medicare *only* if adequate documentation of medical necessity is provided on a case-by-case basis. Obtain advice from your medical consultants or from appropriate specialty physicians or groups in your locality regarding the adequacy of documentation before deciding whether a particular claim should be covered.

A second type of pacemaker surgery that is sometimes performed involves the use of the *thoracic* method of implantation, which requires open surgery. Where the thoracic method is employed, general anesthesia is always used and should not require special medical documentation.

35–81 TREATMENT OF KIDNEY STONES.

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

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

A. *Extracorporeal Shock Wave Lithotripsy.*—Extracorporeal Shock Wave Lithotripsy (ESWL) is a non-invasive method of treating kidney stones using a device called a lithotriptor. The lithotriptor uses shock waves generated outside of the body to break up upper urinary tract stones; it focuses the shock waves specifically on stones under X-ray visualization, pulverizing them by repeated shocks.

ESWL is covered under Medicare for use in the treatment of upper urinary tract kidney stones.

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

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

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

35–82 PANCREAS TRANSPLANTS—Not Covered.

Pancreas transplants of any type are considered investigational and are, therefore, not covered under Medicare.

35–83 24–HOUR AMBULATORY ESOPHAGEAL pH MONITORING—(Effective for services performed on or after 6–11–85).

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

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

35–84 STEREOTACTIC CINGULOTOMY AS A MEANS OF PSYCHOSURGERY—NOT COVERED.

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

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

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

35–85 IMPLANTATION OF AUTOMATIC DEFIBRILLATORS (Effective for services performed on and after 1–24–86).

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. The implantation of an automatic defibrillator is a covered service only when used as a treatment of last resort for patients who have had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction. Patients must also be found, by electrophysiologic testing, to have an inducible tachyarrhythmia that proves unresponsive to medication or surgical therapy (or be considered unsuitable candidates for surgical therapy).

It must be emphasized that unless *all* of the above described conditions and stipulations are met in a particular case, *including the inducibility of tachyarrhythmia, etc.*, implantation of an automatic deibrillator *cannot* be covered.

35–86 GASTRIC BALLOON FOR TREATMENT OF OBESITY—NOT COVERED.

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

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

35–87 HEART TRANSPLANTS—(Effective for services rendered on or after October 17, 1986.)

A. *General.*—Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. (See HCFA Ruling 87–1.)

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

Although consortium arrangements will not be approved for payment of Medicare heart transplants, consideration will be given to application from heart transplant facilities that consist of more than one hospital where *all* of the following conditions exist:

- The hospitals are under the common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally-constituted medical research institute; and
- The hospitals share resources by routinely using the same personnel or services in their transplant programs. The sharing of resources must be supported by the submission of operative notes or other information that documents the routine use of the same personnel and services in all of the individual hospitals. At a minimum, shared resources means:

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

function as members of the transplant team; and

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

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

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

C. *Pediatric Hospitals.*—Cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which HCFA approves as documenting that:

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

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

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

D. *Follow-up Care.*—Follow-up care required as a result of a covered heart transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hosptial after receiving a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See Intermediary Manual § 3101.14 and Carriers Manual § 2300.1.)

E. *Immunosuppressive Drugs.*—(See Intermediary Manual § 3660.8 and Carriers Manual §§ 2050.5, 4471 and 5249.)

F. *Artificial Hearts.*—Medicare does not cover the use of artificial hearts or ventricular assist devices, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant (often referred to as a "bridge to transplant"). (See § 65–15.)

35–88 EXTRACORPOREAL PHOTOPHERESIS (Effective for services performed on or after April 8, 1988.)

Extracorporeal photophereses is a treatment for cutaneous T-cell lymphoma (CTCL), a condition that is generally resistant to chemotherapy and radiotherapy. The treatment begins with the oral administration of the drug methoxsalen. The patient's blood is then passed through a device that permits exposure of the blood, while it is outside the body (extracorporeal), to ultraviolet A light. The blood is then returned to the patient.

Extrcorporeal photopheresis is covered by Medicare only when used in the palliative treatment of skin manifestations of CTCL that has not responded to other therapy.

45 SUPPLIES—DRUGS

45–1 L-DOPA

A. *Part A Reimbursement for L-Dopa and Associated Inpatient Hospital Services.*—A hospital stay and related ancillary services for the administration of L-Dopa are covered if medically required for this purpose. Whether a drug represents an allowable inpatient hospital cost during such stay depends on whether it meets the definition of a drug in section 1861(t) of the law; i.e., on its inclusion in the compendia named in the law or approval by the hospital's pharmacy and drug therapeutics (P&DT) or equivalent committee. (Levodopa (L-Dopa) has been favorably evaluated for the treatment of Parkisonism by A.M.A. Drug Evaluations, First Edition 1971, the replacement compendia for "New Drugs."

Inpatient hospital services are frequently *not* required in many cases when L-Dopa therapy is initiated. Therefore, the medical need for inpatient hospital services must be determined on the basis of medical facts in the individual case. It is not necessary to hospitalize the typical, well-functioning, ambulatory Parkinsonian patient who has no concurrent disease at the start of L-Dopa treatment. It *is* reasonable to provide inpatient hospital services for Parkinsonian patients with concurrent diseases, particularly of the cardiovascular, gastrointestinal, and neuropsychiatric systems. Although many patients may require hospitalization for a period of under 2 weeks, a 4-week period of inpatient care is not unreasonable.

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

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

Physical therapy furnished in connection with administration of L-Dopa.—Where, following administration of the drug, the patient experiences a reduction of rigidity which permits the reestablishment of a restorative goal for him, physical therapy services required to enable him to achieve this goal are reimbursable provided they require the skills of a qualified physical therapist and are furnished by or under the supervision of such a therapist. However, once the individual's restoration potential has been achieved, the services required to maintain him at this level do not generally require the skills of a qualified physical therapist. In such situations the role of the therapist is to evaluate the patient's needs in consultation with his physician, design a program of exercise appropriate to the capacity and tolerance of the patient and treatment objectives of the physician, leaving to others the actual carrying out of the program. While the evaluative services rendered by a qualified physical therapist are reimburseable as physical therapy, services furnished by others in connection with the carrying out of the maintenance program established by the therapist are not.

Cross refer: Intermediary Manual, § 3101.3; Carriers Manual, § 2050.5.

B. *Part A Reimbursement for L-Dopa Therapy in SNFs.*—Initiation of L-Dopa therapy can be appropriately carried out in the SNF setting, applying the same guidelines used for initiation of L-Dopa therapy in the hospital, including the types of patients who should be covered by inpatient services, the role of physical therapy, and the use of laboratory tests. (See subsection A.)

Where inpatient care is required and L-Dopa therapy is initiated in the SNF, limit the stay to a maximum of 4 weeks; but in many cases the need maybe no longer than 1 or 2 weeks, depending upon the patient's condition. However, where L-Dopa therapy is begun in the hospital and the patient is transferred to an SNF for continuation of the therapy, a combined length of stay in hospital and SNF of no longer than 4 weeks is reasonable (i.e., 1 week hospital stay followed by 3 weeks SNF stay; or 2

weeks hospital stay followed by 2 weeks SNF stay; etc.). Medical need must be demonstrated in cases where the combined length of stay in hospital and SNF is longer than 4 weeks. The choice of hospital or SNF, and the decision regarding the relative length of time spent in each, should be left to the medical judgment of the treating physician.

Cross refer: Intermediary Manual, § 3133.5.

C. *L-Dopa Coverage Under Part B.*—Part B reimbursement may not be made for the drug L-Dopa since it is a self-administrable drug. (See Intermediary Manual, § 3112.4B; Carriers Manual, § 2050.5B; Hospital Manual § 230.4B.) However, physician services rendered in conneciton with its administration and control of its side effects are covered if determined to be reasonable and necessary. Initiation of L-Dopa therapy on an outpatient basis is possible in most cases. Visit frequency ranging from every week to every 2 or 3 months is aceptable. However, after half a year of therapy, visits more frequent than every month would usually not be reasonable.

45–3 INSULIN SYRINGE

Medical supplies are covered under § 1861(s)(2)(A) of the law only when they are furnished incident to a physician's professional services. To be covered under this provision an insulin syringe must have been used by the physician or under his direct personal supervision, and the insulin injection must have been given in an emergency situation (e.g., diabetic coma).

The use of an insulin syringe by a diabetic would not meet the requirements of § 1861(s)(2)(A) of the Act.

Cross-refer: Intermediary Manual, § 3112.4B; Carriers Manual, § 2050

45–4 VITAMIN B12 INJECTIONS TO STRENGTHEN TENDONS, LIGAMENTS, ETC., OF THE FOOT—NOT COVERED

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

Cross-refer: Intermediary Manual, §§ 3101.3, 3158; Carriers Manual, §§ 2050.5, 2323.

45–7 HYDROPHILIC CONTACT LENS FOR CORNEAL BANDAGE

Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology, such as bullous keratopathy, dry eyes, corneal ulcers and erosion, keratitis, and for other therapeutic reasons.

Payment may be made under § 1861(s)(2) of the law for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician's service. Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See § 65–1 for coverage of a hydrophilic contact lens as a prosthetic device.)

Cross-refer: Intermediary Manual, § 3112–4; Carriers Manual, § 2050.1.

45–10 LAETRILE AND RELATED SUBSTANCES—NOT COVERED.

Laetrile (and the other drugs called by the various terms mentioned below) have been used primarily in the treatment or "control" of cancer. Although the terms "Laetrile," "laetrile," "amygdalin," "Sarcarcinase," "vitamin B–17," and "nitriloside" have been used interchangeably, the chemical identity of the substances to which these terms refer has varied.

The FDA has determined that neither Laetrile nor any other drug called by the various terms mentioned above, nor any other product which might be characterized as a "nitriloside" is generally recognized (by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs) to be safe and effective for any therapeutic use. Therefore, use of this drug cannot be considered to be reasonable and necessary within the meaning of § 1862(a)(1) of the law and program payment may not be made for its use or any services furnished in connection with its administration.

A hospital stay only for the purpose of having laetrile (or any other drug called by the terms mentioned above) administered is not covered. Also, program payment may not be made for laetrile (or other drug noted above) when it is used during the course of an otherwise covered hospital stay, since the FDA has found such drugs to not be safe and effective for any therapeutic purpose.

45–11 AUTOGENOUS EPIDURAL BLOOD GRAFT (Effective for services performed on and after March 1, 1980)

Autogenous epidural blood grafts are considered a safe and effective remedy for severe headaches that may occur after performance of spinal anesthesia, spinal taps or myelograms, and are covered. In the procedure blood is removed from the patient's vein and injected into his epidural space, to seal the spinal fluid leak and stop the pain.

45–12 PORCINE SKIN AND GRADIENT PRESSURE DRESSINGS

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

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

45–15 PHYSICIAN'S OFFICE WITHIN AN INSTITUTION—COVERAGE OF SERVICES AND SUPPLIES INCIDENT TO A PHYSICIAN'S SERVICES

Where a physician establishes an office within a nursing home or other institution, coverage of services and supplies furnished in the office must be determined in accordance with the "incident to a physician's professional service" provision (see Intermediary Manual, § 3112.4A or Carriers Manual, § 2050.1), as in any physician's office. A physician's office within an institution must be confined to a separately identified part of the facility which is used solely as the physician's office and cannot be construed to extend throughout the entire institution. Thus, services performed outside the "office" area would be subject to the coverage rules applicable to services furnished outside the office setting.

In order to accurately apply the criteria in § 3112.4 or § 2050.1, give consideration to the physical proximity of the institution and physician's office. When his office is located within a facility, a physician may not be reimbursed for services, supplies, and use of equipment which fall outside the scope of services "commonly furnished" in physician's offices generally, even though such services may be furnished in his institutional office. Additionally, make a distinction between the physician's office practice and the institution, especially when the physician is administrator or owner of the facility. Thus, for their services to be covered under the criteria in § 3112.4A

or § 2050.1, the auxiliary medical personnel must be members of the office staff rather than of the institution's staff, and the cost of supplies must represent an expense to the physician's office practice. Finally, services performed by the employees of the physician outside the "office" area must be *directly* supervised by the physician; his presence in the facility as a whole would not suffice to meet this requirement. (In *any* setting, of course, supervision of auxiliary personnel in and of itself is not considered a "physician's professional service" to which the services of the auxiliary personnel could be an incidental part, i.e., in addition to supervision, the physician must perform or have performed a personal professional service to the patient to which the services of the auxiliary personnel could be considered an incidental part). Denials for failure to meet any of these requirements would be based on § 1861(s)(2)(A) of the Act.

Establishment of an office within an institution would not modify rules otherwise applicable for determining coverage of the physician's personal professional services within the institution. However, in view of the opportunity afforded to a physician who maintains such an office for rendering services to a sizable number of patients in a short period of time or for performing frequent services for the same patient, claims for physicians' services rendered under such circumstances would require careful evaluation by the carrier to assure that payment is made only for services that are reasonable and necessary.

Cross-refer: Intermediary Manual, § 3112.4A; Carriers Manual, § 2050.1.

45–16 CERTAIN DRUGS DISTRIBUTED BY THE NATIONAL CANCER INSTITUTE (Effective for services furnished on or after October 1, 1980.)

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

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

A. A physician must be registered with the NCI as an investigator by having completed an FD–Form 1573.

B. A written request for the drug, indicating the disease to be treated, must be submitted to the NCI.

C. The use of the drug must be limited to indications outlined in the NCI's guidelines.

D. All adverse reactions must be reported to the Investigational Drug Branch of the Division of Cancer Treatment.

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

If there is reason to question coverage in a particular case, the matter should be resolved with the assistance of the local PSRO, or if there is none, the assistance of your medical consultants.

Information regarding those drugs which are classified as Group C drugs may be obtained from:

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

45–17 TRANSFER FACTOR FOR TREATMENT OF MULTIPLE SCLEROSIS

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

45–18 GRANULOCYTE TRANSFUSIONS

Granulocyte transfusions to patients suffering from severe infection and granulocytopenia are a covered service under Medicare. Granulocytopenia is usually identified as fewer than 500 granulocytes/mm whole blood. Accepted indications for granulocyte transfusions include:

(1) Granulocytopenia with evidence of gram negative sepsis;

(2) Granulocytopenia in febrile patients with local progressive infections unresponsive to appropriate antibiotic therapy, thought to be due to gram negative organisms.

45–19 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) FOR ACUTE POST-OPERATIVE PAIN

The use of transcutaneous electrical nerve stimulation (TENS) for the relief of acute post-operative pain is covered under Medicare. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment or acute pain resuting from surgery.

TENS devices, whether durable or disposable, may be used in furnishing this service. When used for the purpose of treating acute post-operative pain, TENS devices are considered supplies. As such they may be hospital supplies furnished inpatients covered under Part A, or supplies incident to a physician's service when furnished in connection with surgery done on an outpatient basis, and covered under Part B.

It is expected that TENS, when used for acute post-operative pain, will be necessary for relatively short periods of time, usually 30 days or less. In case when TENS is used for longer periods, contractors should attempt to ascertain whether TENS is no longer being used for acute pain but rather for chronic pain, in which case the TENS device may be covered as a prosthetic device as described in section 65–8.

Cross-refer: HCFA Pub. 13–3, §§ 65–8, 3101.4, 3112.4, 3113; HCFA Pub. 14–3, §§ 65–8, 2050.1, 2100; HCFA Pub. 10, §§ 65–8, 210.4, 230, 235.

45–20 ETHYLENEDIAMINE-TETRA-ACETIC (EDTA) CHELATION THERAPY FOR TREATMENT OF ATHEROSCLEROSIS

The use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.

See § 35–64 for an explanation of this conclusion.

45–21 SCALP HYPOTHERMIA DURING CHEMOTHERAPY, TO PREVENT HAIR LOSS

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

While ice-filled bags or bandages or other devices used for scalp hypothermia during chemotherapy may be covered as supplies of the kind

commonly furnished without a separate charge, no separate charge for them would be recognized.

45–22 LYMPHOCYTE IMMUNE GLOBULIN, ANTI-THYMOCYTE GLOBULIN (EQUINE)

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

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

45–23 DIMETHYL SULFOXIDE (DMSO)

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

45–24 ANTI-INHIBITOR COAGULANT COMPLEX (AICC)

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

45–25 SUPPLIES USED IN THE DELIVERY OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) AND NEUROMUSCULAR ELECTRICAL STIMULATION (NMES)—(Effective for services rendered (i.e., items rented or purchased) on or after JULY 14, 1988.)

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

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

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

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

• *One* of the medical indications outlined below is met:

—the patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated *and* the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;

—the patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;

—the patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;

—the patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or

—the patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS devise *during* the trial period specified in § 35–46 *unless*:

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

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

(See conditions for coverage of the use of TENS in the diagnosis and treatment of chronic intractable pain in §§ 35–46 and 65–8A.1 and the use of NMES in the treatment of disuse atrophy in § 35–77.)

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 fequency 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 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 Northern 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 CYOTOXIC 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 Graviee 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 (§ 1862(a)(7) of the Act).

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

50–5 THERMOGRAPHY

Thermography is a procedure which relies upon measurement of infrared radiation from the body for diagnostic purposes. Its use is indicated when disease is suspected and not as a screening device for ostensibly healthy individuals. Thermography must be performed by a physician or under his direct supervision; however, only a physician can interpret the results.

The use of thermography for the following indications is covered:

- Peripheral vascular disease (e.g., thrombophlebitis, arterial insufficiency);
- Musculoskeletal injury (e.g., low back injury involving musculoligamentous soft tissue or herniated disc); and
- Cervical thermography for diagnosis of extra-cranial vessel disease causing CNS symptoms (carotid insufficiency), and for diagnosis of inflammatory, neoplastic, and hyperplastic lesions.

The following are some examples, by category, of the use of cervical thermography in diagnosing lesions:

—Inflammatory lesions:
  *Soft tissue injury (e.g., whiplash);
  *Presence of a foreign body (e.g., loa loa, a filarial roundworm infestation);
—Neoplastic lesions:
  *Parathyroid adenoma;
  *Isotopically cold thyroid nodule;
  *Tumor of the larynx with metastases to neck lymph modes; and
—Hyperplastic lesions:
  *Parathyroid adenoma;
  *Isotopically hot thyroid nodule.

The use of thermography for the following indication is excluded from coverage effective for services rendered on and after July 20, 1984.

Detection of breast disease.

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 would 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 should be 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 law.

CATEGORY I

Segmental Plethysmography—Included under this procedure are services performed with a regional plethysmograph, differential plethysmograph, recording oscillometer, 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.

Strain Gauge Plethysmography—This method is still considered experimental, does not provide consistent results, and is therefore not suitable for routine office use.

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 exlusions, 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.

50–9 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 (section 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:

- The model must be known to the Food and Drug Administration, and
- 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 1986."

b. A letter signed by the chief executive officer or other officer acting in a similar capactity 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 or 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 (MIPDI).*—(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 muclei 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 for 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 contract resolution without injected inodiated contrast agents. Recent advances in technology have resulted in development 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 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 C. below), MRI is considered medically efficacious for a number of uses. Contractors should 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 premarket approval by the Food and Drug Administration; 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. Although MRI can be used to detect degeneration of intervertebral discs, radiological imaging is the preferred modality for diagnosing disc herniation or prolapse. However, in some cases, especially when sensitivity to radiological contrast agents exists and their use is contraindicated, MRI may be covered.

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. 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 neoplasms 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.

C. *Contraindications and investigational 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. *Investigational uses.*—Several uses of MRI have been identified as investigational and are not covered. These include procedures involving gating devices, which are generally used on organs which are in motion, such as the heart or lungs, the measurement of blood flow and spectroscopy. In addition, MRI is not suitable for the imaging of cortical bone and calcifications, or for procedures involving spatial resolution of bone or calcifications.

The use of surface RF coils, whether for sending or receiving RF signals, in conjunction with MRI procedures, is also considered investigational.

50–15 ELECTROCARDIOGRAPHIC SERVICES

Reimbursement may be made under Part B for electrocardiographic services rendered by a physician or incident to his 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 should be allowed only where it is the normal practice to make such charge in addition to the regular office visit charge. No payment should be made for EKG interpretations by individuals other than physicians.

A claim involving EKG services furnished by a *laboratory* or a *portable X-ray supplier* should identify the physician ordering the service and, where the charge includes both the taking of the tracing and its interpretation, the identity of the physician making the interpretation. No separate bill for the services of a physician should be paid unless it is clear that he was the patient's attending physician or was acting as a consulting physician. The taking of an EKG in an emergency, i.e., where the patient is or may be experiencing what is commonly referred to as a "heart atack," would be covered as a laboratory service or a diagnostic service by a portable X-ray supplier only where 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-arrhythemic 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 enable 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 mycardial 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-time 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 symptons 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 activty. 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 physicially transport the tape. Some of thes 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 electrocardigraphic 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 of 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 reimbursement 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 should not be 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 progess of CRD patients. The following list and frequencies of tests constitutes 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

Hematocrit

Per Week

Prothrombin time for patients on anti-coagulant therapy
Serum Creatinine
BUN

Monthly

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

Guidelines for tests other than those routinely performed include:

Bone survey, either the roentgenographic method or the photon absorptiometric procedure for bone mineral analysis-annually.

The frequency of the need to perform "bone surveys" varies with many factors, some of which are the age of the patient (e.g., children and the elderly), clinical symptoms (e.g., bone pain, evidence of metastatic calcification), abnormal laboratory tests) e.g., changes in alkaline phosphatase, calcium, phosphorus), and because of therapeutic intervention directed at forestalling or improving pre-exisitng or potential bone disease (e.g., vitamin D, calcium supplments, parathyroidectomy). Where any of these factors apply to the beneficiary, claims for "bone surveys" performed on a frequency more often than annually need only have minimal documentation of medical need.

Nerve conductor velocity test (peritoneal NCV)—once every 3 months.

EKG—once very 3 months.

Chest X-ray—once every 6 months (effective for services rendered on or after December 1, 1978).

Hepatitis associated antigen tests—once a month. (These tests previously were subject to a guideline limit of once a quarter. While their category has been changed so that they now can be provided once a month without additional documentation, they should

be billed for separately because the reimbursement screens for maintenance dialysis treatments did not take them into account).

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

50–18 ELECTRON MICROSCOPE

The electron microscope has been used in the examination of biopsies for years and its efficacy, and therefore its Medicare coverage, is not being questioned. However, there also are other 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, program payment will be based upon the less costly methods of examining biopsies.

50–19 PRONOUNCEMENT OF DEATH

According to estabished 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 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 PAP SMEARS (Effective for pap smears performed on or after May 15, 1978.)

The pap smear is a diagnostic test which can show the absence or presence of one or more of the following conditions: trauma, infection, carcinogens, and viruses. The test is also frequently part of a routine physical examination; as such, it is not a covered Medicare service. A pap smear may be covered under the following conditions: (1) Previous cancer of the cervix, uterus, or vagina which has been or is presently being treated, (2) Previous abnormal pap smear, (3) Any abnormal findings of the vagina, cervix, uterus, ovaries, or adnexa, (4) Any significant complaint by the patient referrable to the female reproductive system, or (5) any signs or symptoms which might in the physician's judgment reasonably be related to gynecologic disorder.

In respect to number five (5) above, the intermediary's medical staff should determine whether in a particular case a previous malignancy at another site is a diagnostic indication for a pap smear so that the test would not be considered part of a routine screening.

Cross-refer: HCFA 13–3, §§ 3101.5; HCFA 14–3, § 2070.

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: (1) A patient has distinct signs and symptoms for which a mammogram is indicated, (2) A patient has a history of breast cancer, or (3) 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: HCFA 13–3, §§ 3101.5; HCFA 14–3, § 2070.

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 may be 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 may be 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 transplant;

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 Intermediary Manual, §§ 3020.2; 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

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

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: (1) Genetic disorders (e.g., mongolism) in a fetus (See Intermediary Manual, § 3101.13); (2) Failure of sexual development; or (3) Chronic myelogenous leukemia.

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 EVOKED 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 test measure brain responses to repetitive visual, click or other stimuli. Program payment may be made for these procedures.

50–32 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE TREATMENT OF ARTERIOSCLEROTIC OBSTRUCTIONS IN THE LOWER EXTREMITIES (EFFECTIVE FOR SERVICES PERFORMED ON AND AFTER MAY 15, 1981.)

This procedure involves inserting a balloon catheter into a narrow or occluded artery in order to recanalize and dilate the artery by inflating the balloon. PTA in the treatment of arteriosclerotic obstructions in the lower extremities—i.e., the iliac, femoral, and popliteal arteries—is a covered service.

50–32.1 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) IN THE TREATMENT OF STENOTIC LESIONS OF A SINGLE CORONARY ARTERY (EFFECTIVE FOR SERVICES PERFORMED ON AND AFTER 11–22–85.)

PTCA, a percutaneous transluminal angioplasty procedure performed in the coronary artery, is covered for treatment of stenotic lesions of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery, and who have the following characteristics:

Angina refractory to optimal medical management;

Objective evidence of myocardial ischemia; and

Lesions amenable to angioplasty.

50–32.2 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE TREATMENT OF STENOTIC LESIONS OF THE RENAL ARTERIES (EFFECTIVE FOR SERVICES PERFORMED ON AND AFTER MARCH 21, 1983.)

PTA in the treatment of stenotic lesions of the renal arteries is a covered procedure for a limited group of patients. This group comprises those 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.

50–32.3 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE TREATMENT OF OBSTRUCTIVE LESIONS OF THE AORTIC ARCH VESSELS—NOT COVERED

PTA in the treatment of obstructive lesions of the aortic arch vessels, including the carotid, subclavian, and vertebral arteries, is excluded from

coverage. This treatment is a relatively new procedure whose safety and efficacy has not yet been established.

50–32.4 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE TREATMENT OF OBSTRUCTIVE LESIONS OF ARTERIOVENOUS DIALYSIS FISTULAS—NOT COVERED

The use of PTA to dilate failing arteriovenous dialysis fistulas and shunts is excluded from coverage. This recent application of PTA has rarely been performed. More experience in controlled studies is needed to better define the safety and effectiveness of this procedure.

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

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

The following diagnostic tests should not be paid for routinely becaused they are obsolete and have been replaced by more advanced procedures. This listed tests may be paid for only if the medical need for the procedure is satisfactorily justified by the physician who performs it. Where a PSRO is responsible for reviewing the services for which payment is claimed, the determination that satisfactory justification of medical necessity exists is the PSRO's responsibility. Where the services are not subject to PSRO review, the intermediary or carrier is responsible for determining that satisfactory medical justification exists:

—amylase, blood isoenzymes, electrophoretic
—chromium, blood
—guanase, blood
—zinc sulphate turbidiaty, blood
—skin test, cat scratch fever
—skin test, lymphopathia venereum
—circulation time, one test
—cephalin flocculation
—congo red, blood
—hormones, adrenocorticotropin quantitative animal tests
—hormones, adrenocorticotropin quantitative bioassay
—thymol turbidity, blood
—skin test, actinomycosis
—skin test, brucellosis
—skin test, psittacosis
—skin test, trichinosis
—calcium, feces, 24-hour quantiative
—starch, feces, screening
—chymotrypsin, duodenal contents
—gastric analysis pepsin
—gastric analysis, tubeless
—calcium saturation clotting time
—capillary fragility test (Rumpel-Leede)
—colloidal gold

Effective for services performed on and after July 31, 1982, the following additional diagnostic tests are added:

—Bendien's test for cancer and tuberculosis
—Bolen's test for cancer
—Rehfuss test for gastric acidity

Effective for services performed on and after December 3, 1982, the following diagnostic test is added:

—Serum seromucoid assay for cancer and other diseases

50–35 SWEAT TEST

(Effective for services performed on and after September 30, 1980).

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 in unproven and, therefore, is not covered.

50–36 POSITRON EMISSION TRANSVERSE TOMOGRAPHY (PETT) SCANS—NOT COVERED

Positron emission transverse tomography (PETT) scans are a new type of scanning system currently in the experimental stage of development. Since this is considered an experimental technology, no payment may be made under Medicare for such scans.

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 disal 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 PHOTOGRAPH

(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:

1. Have slit lamp evidence of endothelial dystrophy (cornea guttata).
2. Have slit lamp evidence of corneal edema (unilateral or bilateral).
3. Are about to undergo a secondary intraocular lens implantation.
4. Have had previous intraocular surgery and require cataract surgery.
5. Are about to undergo a surgical procedure associated with a higher risk to corneal endothelium; ie., phacoemulsification, or refractive surgery. (See § 35–54 for excluded refractive procedures.)
6. With evidence of posterior polymorphous dystrophy of the cornea or iridocorneal-endothelium syndrome.
7. Are about to be fitted with extended wear contact lenses after intraocular surgery.

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:

A. Altered consciousness, such as stuporous, semicomatose, or comatose states;

B. Atypical seizure variants in patients experiencing bizarre, distressing symptoms as seen with "spike and wave stupor" or other forms of seizure disorders;

C. Diagnosis of a suspected intracranial tumor;

D. Head injury, where a subdural hematoma may be identified;

E. 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.

50–42 AMBULATORY BLOOD PRESSURE MONITORING WITH FULLY AND SEMI-AUTOMATIC (PATIENT-ACTIVATED) PORTABLE MONITORS—NOT COVERED

While ambulatory blood pressure monitoring in hypertensive patients using fully and semi-automatic (patient-activated) portable monitors is a safe and accurate means of measuring blood pressure, the clinical usefulness of the data obtained from such devices is not clearly established. Researchers and clinicians cite the need for standardization of instrumentation and further study of this technology to better ascertain its role in hypertensive therapy. Accordingly, program payment may not be made for the use of such devices at this time.

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 HCFA 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 disease 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 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 (CIG) AS AN ALTERNATIVE TO STRESS TEST OR THALLIUM STRESS TEST—NOT COVERED

A cardiointegram 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 physician's 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 cardiokymography and photokymography, is a noninvasive diagnostic test used in evaluating coronary artery disease.

A. *Cardiokymography.*—(Effective for services rendered on or after October 12, 1988).

Cardiokymography 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:

- For male patients, atypical angina pectoris or nonischemic chest pain; or
- 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:

- 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.
- $^{13}CO_2$ for diagnosing bile acid malabsorption, effective for services rendered on and after June 12, 1984.
- $^{13}CO_2$ for diagnosing fat malabsorption, effective for services rendered on and after June 12, 1984.

50–52 SEROLOGIC TESTING FOR A 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.

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 or magnesium and calcium (causing hardness), compounds of fluoride and chloride from tap water using the process of filtration and ion exchange; or

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

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

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

B. *Water Softening System.*—Except as indicated below, a water softening system used in conjunction with home dialysis is excluded from coverage under Medicare as not being reasonable and necessary within the meaning of § 1862(a)(1) of the 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:

- The manufacturer of the RO unit has set standards for the quality of water entering the RO (e.g., the water to be purified by the RO must be of a certain quality if the unit is to perform as intended);
- The patient's water is demonstrated to be of a lesser quality than required; and
- The softener is used only to soften water entering the RO unit, and thus, used only for dialysis. (The softener need not actually be built into the RO unit, but must be an integral part of the dialysis *system.*)

C. *Developing Need When a Water Softening System is Replaced with a Water Purification Unit in an Existing Home Dialysis System.*—The medical necessity of water purification units must be 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, §§ 3113, 3643 (item 1c); Carriers Manual, §§ 2100, 2100.2 2130, 2105 (item 1c); Hospital Manual, § 235.

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.

60–3 WHITE CANE FOR USE BY A BLIND PERSON–NOT COVERED

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

60–4 HOME USE OF OXYGEN

A. *General.*–Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment benefit (§ 1861(s)(6)) will be considered reasonable and necessary *only* for patients with significant hypoxemia who meet the medical documentation, laboratory evidence and health conditions specified in subsections B, C

and D. This section also includes special coverage criteria for portable oxygen systems in subsection E. Special requirements for patients already covered under a program of home oxygen therapy as of September 30, 1985, are described in subsection F. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection G.

B. *Medical Documentation.—Initial* claims for oxygen services *must* include a short written statement from the attending physician indicating that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchiospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, it is appropriate that each patient should receive optimum therapy before long-term home oxygen therapy is ordered.

Initial claims for oxygen services *must* also be supported by medical documentation (separate documentation where electronic billing is used), such as a prescription, written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) that specifies:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and

NOTE: All claims with flow rates of more than 2 liters per minute *must* be reviewed by a carrier's medical staff before payment can be made.

- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minuts per hour, 12-hours a day) and duration of need (e.g., 6 months or lifetime).

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

The attending physician may also specify the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator). If the type of system is specified, then the medical reasons for selecting that system over the alternative systems must also be specified.

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

Carriers are required to conduct periodic, continuing medical necessity review on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in Carriers Manual, Part 3, § 4105.2B. Where indicated, carriers may also request documentation of the results of a repeat arterial blood gas or oximetry study. (See subsection C.)

C. *Laboratory Evidence.—Initial* claims for oxygen therapy *must* also include the results of a blood gas study that has been ordered and evaluated by the attenting physician. This will *usually* be in the form of a measurement of the partial pressure of oxygen (PO_2) in arterial blood. (See Carriers Manual, Part 3, § 2070.1 for instructions on clinical laboratory tests.) A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, will also be acceptable when ordered and evaluated by the attending physician *and* performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services. A DME supplier will not be considered a qualified provider or supplier of laboratory services for purposes of these guidelines. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the *initial* claim, i.e., at rest, while sleeping, while exercising, on room air, or if while on oxygen, the amount, body position during testing, and similar information necessary for interpreting the evidence as specified by the carrier.

The preferred sources of laboratory evidence are existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines would have recently been discharged from a hospital where they submitted to arterial blood gas tests, the carrier should request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed during the patient's hospital stay, the test result obtained closest to the hospital discharge date would be the best evidence of the need for home oxygen therapy. Carriers may accept an attending physician's statement of recent hospital test results for a particular patient, where appropriate, in lieu of copies of actual hospital records. Subsequent blood gas tests that appear to duplicate the hospital test (e.g., where there is no reason to believe the patient's condition may have changed) should be denied as not medically reasonable and necessary.

A repeat arterial blood gas or oximetry study will normally be necessary only where evidence indicates that an oxygen recipient has undergone a *major* change relevant to home use of oxygen. For example, if the carrier has reason to believe that there has been a major change in the patient's physical condition (e.g., where there has been a significant increase in the amount of oxygen billed on a monthly basis) it may ask for documentation of the results of another blood gas or oximetry study.

D. *Health Conditions.*—Coverage is available for patients with significant hypoxemia in the chronic stable state if: (1) the attending physician has determined that the patient has a health condition outlined in subsection D.1, (2) the patient meets the blood gas evidence requirements specified in subsection D.3, and (3) the patient has appropriately tried other alternative treatment measures without complete success. (See subsection B1.)

1. *Conditions for Which Oxygen Therapy May Be Covered.—*

- A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, whether of known or unknown etiology; cystic fibrosis bronchiectasis; widespread pulmonary neoplasm; or
- Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2. *Conditions for Which Oxygen Therapy Is Not Covered.—*

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood and there are other preferred treatments.
- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting.
- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO_2 will improve the oxygenation of tissues with impaired circulation.
- Terminal illnesses that do not affect the lungs.

3. *Covered Blood Gas Values.*—If the patient has a condition specified in subsection D.1., the carrier must review

the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below:

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

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

(2) An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken *during sleep* for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, while awake; or a greater than normal fall in oxygen level *during sleep* (a decrease in arterial PO_2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5 percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided *only* for *nocturnal* use of oxygen.

(3) An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken *during exercise* for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, during the day while at rest. In this case, supplemental oxygen is provided for *during exercise* if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

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

(1) Dependent edema suggesting congestive heart failure;

(2) "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or

(3) Erythrocythemia with a hematocrit greater than 56 percent.

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

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

E. *Portable Oxygen Systems.*—A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or, (2) to complement a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- The claim meets the requirements specified in subsections A–D, as appropriate; and
- The medical documentation includes a description of the activities or exercise routine (e.g., amount and frequency of ambulation) that the patient undertakes on a regular basis, and that requires the portable system in the home. The documentation must describe the medical therapeutic purpose to be served by the portable system that cannot be met by a stationary system.

F. *Patients Covered Under a Program of Home Oxygen as of September 30, 1985.*—Patients who have already been determined by the carrier to be covered under a program of home oxygen (either for stationary *and* portable systems or just a stationary system) as of September 30, 1985, must meet the following requirements in order to continue to received coverage after that date:

1. *Medical Need Already Established.*—Where the carrier has already received documentation of the medical need for oxygen services for such patients, as specified in subsections A–E, new documentation is not required regardless of when the existing documentation was submitted. However, the patient's continuing need for oxygen services must be periodically verified as specified in Carriers Manual, Part 3, § 4105.2.

2. *Medical Need Not Established.*—Where documentation of the medical need for oxygen services for such patients, as specified in subsections A–E, has not submitted to the appropriate carrier, the following provisions will apply:

a. *Up to October 1, 1986.*—The carrier will continue to reimburse for oxygen services furnished up to October 1, 1986. During this 12-month grace period, the carrier will continue to apply the local requirements in effect before October 1, 1985 and will continue to verify the patient's medical need for oxygen services according to the review procedures described in Carriers Manual, Part 3, § 4105.2.

b. *After October 1, 1986.*—Except as provided in subsection c, the carrier will not reimburse for oxygen services furnished later than October 1, 1986 unless:

- the documentation specified in subsections A–E is submitted to the carrier; and
- the carrier makes a determination that the oxygen services are covered.

c. *Exception.*—if the patient does not meet the criteria specified in subsections A–E, the carrier reimburses for oxygen services furnished after October 1, 1986 *only* if:

- There is a medical risk that the patient's condition could be complicated by his withdrawal from oxygen (e.g., where the patient has a physhological dependence on oxygen) and the attending physician certifies that there is a continuing medical need for the patient to receive oxygen; and
- The carrier makes a determination that the services *are* covered.

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

Cross-Refer: Intermediary Manual, Part 3, §§ 3113ff; Carriers Manual, Part 3, §§ 2100ff; § 60–9.

60–5 POWER-OPERATED VEHICLES THAT MAY BE USED AS WHEELCHAIRS

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

These vehicles have been appropriately used in the home setting for vocational rehabilitation and to improve the ability of chronically disabled persons to cope with normal domestic, vocational and social activities. They may be covered if a wheelchair is medically necessary and the patient is unable to operate a wheelchair manually.

A specialist in physical medicine, orthopedic surgery, neuology, or rheumatology must provide an

evaluation of the patient's medical and physical condition and a prescription for the vehicle to assure that the patient requires the vehicle and is capable of using it safely. Where an intermediary determines that such a specialist is not reasonably accessible, e.g., more than 1 day's round trip from the beneficiary's home, or the patient's condition precludes such travel, a prescription from the beneficiary's physician is acceptable.

The intermediary's medical staff reviews all claims for a power-operated vehicle, including the specialists' or other physicians' prescriptions and evaluations of the patient's medical and physical conditions, to insure that all coverage requirements are met.

Cross-refer: Intermediary Manual, Part 3, § 3643; see wheelchairs in § 60–9.

60–6 SPECIALLY SIZED WHEELCHAIRS

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

A physician's certification or prescription that a special size is needed is not required where you can determine from the information in file or other sources that a specially sized wheelchair (rather than a standard one) is needed to accommodate the wheelchair to the place of use or the physical size of the patient.

To determine the reasonable charge in these cases, use the criteria set out in Carriers Manual, §§ 5022, 5022.1, 5200, and 5205, as necessary.

Cross-refer: Intermediary Manual, §§ 3113.2C, 3642.1, 3643 (item 3); Carriers Manual, §§ 2100.2c, 2105, 4105.2, 5107; Hospital Manual, §§ 235.2c, 420.1 (item 13).

60–7 SELF-CONTAINED PACEMAKER MONITORS

Self-contained pacemaker monitors are accepted devices for monitoring cardiac pacemakers. Accordingly, program payment may be made for the rental or purchase of either of the following pacemaker monitors when it is prescribed by a physician for a patient with a cardiac pacemaker:

A. *Digitial Electronic Pacemaker Monitor.*—This device provides the patient with an instantaneous digital readout of his pacemaker pulse rate. Use of this device does not involve professional services until there has been a change of five pulses (or more) per minute above or below the initial rate of the pacemaker; when such change occurs, the patient contacts his physician.

B. *Audible/Visible Signal Pacemaker Monitor.*—This device produces an audible and visible signal which indicates the pacemaker rate. Use of this device does not involve professional services until a change occurs in these signals; at such time, the patient contacts his physician.

NOTE: The design of the self-contained pacemaker monitor makes it possible for the patient to monitor his pacemaker periodically and minimizes the need for regular visits to the outpatient department of the provider.

Therefore, documentation of the medical necessity for pacemaker evaluation in the outpatient department of the provider should be obtained where such evaluation is employed in addition to the self-contained pacemaker monitor used by the patient in his home.

Cross-refer: § 50–1.

60–8 SEAT LIFT

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

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

Cross Refer: Carriers Manual, § 5107.

60–9 DURABLE MEDICAL EQUIPMENT REFERENCE LIST.

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

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

When you receive a claim for an item of equipment which does not appear to fall logically into any of the *generic* categories listed, you have the authority and responsibility for deciding whether those items are covered under the DME benefit. These decisions must be made by each contractor based on the advice of its medical consultants, taking into account:

- The general DME coverage instructions in the Carriers Manual, § 2100ff and Intermediary Manual, § 3113ff (see below for brief summary);
- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) (see Carriers Manual, § 2303.1 and Intermediary Manual, § 3151.1) and is otherwise generally considered to be safe and effective for the purpose intended; and
- Whether the item is reasonable and necessary for the individual patient.

As provided in the Carriers Manual, § 2100.1, and Intermediary Manual, § 3113.1, the term DME is defined as equipment which·

- Can withstand repeated use; i.e., could normally be rented, and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;

Generally is not useful to a person in the absence of illness or injury; and

• Is appropriate for use in a patient's home.

DURABLE MEDICAL EQUIPMENT REFERENCE LIST

Item	Coverage Status
Air Cleaners	Deny—environmental control equipment; not primarily medical in nature (§ 1861(n) of the Act).
Air Conditioners	Deny—Environmental control equipment; not primarily medical in nature (§ 1861(n) of the Act).
Alternating Pressure Pads, and Mattresses and Lambs Wool Pads.	—Covered if patient has, or is highly susceptible to decubitus ulcers, and patient's physician has specified that he will be supervising its use in connection with his course of treatment.)
Audible/Visible Signal Pacemaker Monitor	(See Self-Contained Pacemaker Monitor.)
Augmentative Communication Device	(See Communicator.)
Bathtub Lifts	Deny—convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Bathtub Seats	Deny—comfort or convenience item; hygienic equipment; not primarily medical in nature (§ 1861(n) of the Act).
Bead Bed	Deny—institutional equipment; inappropriate for home use.
Bed Baths (home type)	Deny—hygienic equipment; not primarily medical in nature (§ 1861(n) of the Act).
Bed Lifter (bed elevator) of the Act	Deny—not primarily medical in nature (§ 1861(n).
Bedboards	Deny—not primarily medical in nature (§ 1861(n) of the Act).
Bad pans (autoclavable hospital type)	Cov;ered if patient is bed confined.
Bed Side Rails	(See Hospital Beds, § 60–18.)
Beads-Lounger (power or manual)	Deny—not a hospital bed; comfort or convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Beds—Oscillating	Deny—institutional equipment; inappropriate for home use.
Bidet Toilet Seat	(See Toilet Seats.)
Blood Glucose Analyzer—Reflectance Colorimeter	Deny—unsuitable for home use (See § 60–11.)
Blood Glucose Monitor	Covered if patient meets certain conditions (See § 60–11.)
Braille Teaching Texts	Deny—education equipment; not primarily medical in nature (§ 1861(n) of the Act).
Canes	Covered if patient's condition impairs ambulation (See § 60–3.)
Carafes	Deny—convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Catheters	Deny—nonreusable disposable supply (§ 1861(n) of the Act).
Commodes	Covered if patient is confined to bed or room. Note: The term "room confined" means that the patient's condition is such that leaving the room is medically contraindicated. The accessibility of bathroom facilities generally would not be a factor in this determinationl. However, confinement of a patient to this home is a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient's medical condition cofines him to a floor of his home and there is no bathroom located on that floor (See Hospital Beds in § 60–18 for definition of "bed confinement".)
Communicator	Deny—convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Continuous Passive Motion (CPM) Devices	Continuous Passive Motion devices are covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within two days following surgery. In addition, coverage is limited to that portion of the three week period following surgery during which the device is used in the patient's home. There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications.
Continuous Positive Airway Pressure (CPAP)	(See § 60–17.)
Crutches	Covered if patient's condition impairs ambulation.
Cushion Lift Power Seat	(See Seat Lifts.)
Dehumidifiers (room or central heating system type)	Deny—environmental control equipment; not primarily medical in nature (§ 1861(n) of the Act).
Diathermy Machines (standard and pulsed wave types)	Deny—inappropriate for home use (See § 35–41.)
Digital Electronic Pacemaker Monitor	(See Self-Contained Pacemaker Monitor.)
Disposable Sheets and Bags	Deny—nonreusable disposable supplies (§ 1861(n) of the Act).
Elastic Stockings	Deny—nonreusable supply; not rental-type items (§ 1861(n) of the Act).
Electric Air Cleaners	Deny—(See Air Cleaners.) (§ 1861(n) of the Act).
Electric Hospital Beds	(See Hospital Beds (See § 60–18.)
Electrostatic Machines	Deny—(See Air Cleaners and Air Conditioners.) (§ 1861(n) of the Act).
Elevators	Deny—convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Emessis Basins	Deny—convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Esophageal Dilator	Deny—physician instrument; inappropriate for patient use.
Exercise Equipment	Deny—not primarily medical in nature (§ 1861(n) of the Act).
Fabric Supports	Deny—nonreusable supplies; not rental-type item (§ 1861(n) of the Act).
Face Masks (oxygen)	Covered if oxygen is covered (See § 60–4.)
Face Masks (surgical)	Deny—nonreusable disposable items (§ 1861(n) of the Act).
Flowmeter	(See Medical Oxygen Regulators.)
Fluidic Breathing Assister	(See IPPB Machines.)
Fomentation Device	(See Heating Pads.)
Gel Flotation Pads and Mattresses	(See Alternating Pressure Pads and Mattresses.)
Grab Bars	Deny—self-help device; not primarily medical in nature (§ 1861(n) and 1862(a)(6) of the Act).
Heat and Massage Foam Cushion Pad	Deny—not primarily medical in nature; personal comfort item (§ 1861(n) and 1862(a)(6) of the Act).
Heating and Cooling Plants	Deny—environmental control equipment; not primarily medical in nature (§ 1861(n) of the Act).
Heating Pads	Covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heating pad is therapeutically effective.
Heat Lamps	Covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heat lamp is therapeutically effective.
Hospital Beds	(See § 60–18.)
Hot Packs	(See Heating Pads.)
Humidifiers (oxygen)	(See Oxygen Humidifiers.)
Humidifiers (room or central heating system types)	Deny—environmental control equipment; not medical in nature (§ 1861(n) of the Act).
Hydraulic Lift	(See Patient Lifts.)
Incontinent Pads	Deny—nonreusable supply; hygienic item (§ 1861(n) of the Act).
Infusion Pumps	For external and implantable pumps, see § 60–14. If the pump is used with an enteral or parenteral nutritional therapy system, see §§ 65–10—65.10.2 for special coverage rules.

DURABLE MEDICAL EQUIPMENT REFERENCE LIST—Continued

Item	Coverage Status
Injectors (hypodermic jet pressure powered devices for injection of insulin).	Deny—effectiveness not adequately demonstrated.
IPPB Machines	Covered if patient's ability to breathe is serverly impaired.
Iron Lungs	(See Ventilators.)
Irrigating Kit	Deny—nonreusable supply; hygienic equipment (§ 1861(n) of the Act).
Lambs Wool Pads pressure pads and mattresses	Covered under same conditions as alternating
Leotards	Deny—(See Pressure Leotards.) (§ 1861(n) of the Act).
Lymphedema Pumps (segmental and non-segmental therapy types).	Covered (See § 60–16.)
Massage Devices	Deny—personal comfort items; not primarily medical in nature (§§ 1861(n) and 1862(a)(6) of the Act).
Mattress	Covered only where hospital bed is medically necessary (Separate Charge for replacement mattress should not be allowed where hospital bed with mattress is rented.) (See § 60–18.)
Medical Oxygen Regulators	Covered if patient's ability to breathe is severely impaired (See § 60–4.)
Mobile Geriatric Chair	(See Rolling Chairs.)
Motorized Wheelchairs	(See Wheelchairs (power operated).)
Muscle Stimulators	Covered for certain conditions (See § 35–77.)
Nebulizers	Covered if patient's ability to breathe is severely impaired.
Oscillating Beds	Deny—institutional equipment—inappropriate for home use.
Overbed Tables	Deny—convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Oxygen	Covered if the oxygen has been prescribed for use in connection with medically necessary durable medical equipment (See § 60–4.)
Oxygen Humidifiers	Covered if a medical humidifier has been prescribed for use in connection with medically necessary durable medical equipment for purposes of moisturizing oxygen (See § 60–4.)
Oxygen Regulators (Medical)	(See Medical Oxygen Regulators.)
Oxygen Tents	(See § 60–4.)
Parafin Bath Units (Portable)	(See Portable Paraffin Bath Units.)
Paraffin Bath Units (Standard)	Deny—institutional equipment; inappropriate for home use.
Parallel Bars	Deny—support exercise equipment; primarily for institutional use; in the home setting other devices (e.g., a walker) satisfy the patient's need.
Patient Lifts	Covered if contractor's medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest or retard deterioration in his condition.
Percussors	Covered for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient or operator of powered percussor has received appropriate training by a physician or therapist, and no one competent to administer manual therapy is available.
Portable Oxygen Systems:	
1. Regulated (adjustable flow rate)	Covered under the conditions specified in § 60–4. Refer all claims to medical staff for this determination.
2. Preset (flow rate not adjustable)	Deny—emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature.
Portable Pariffin Bath Units	Covered when the patient has undergone a successful trial period of paraffin therapy ordered by a physician and the patient's condition is expected to be relieved by long term use of this modality.
Portable Room Heaters	Deny—environmental control equipment; not primarily medical in nature (§ 1861(n) of the Act).
Portable Whirlpool Pumps	Deny—not primarily medical in nature; personal comfort items (§§ 1861(n) and 1862(a)(6) of the Act).
Postural Drainage Boards condition	Covered if patient has a chronic pulmonary.
Preset Portable Oxygen Units	Deny—emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature.
Pressure Leotards	Deny—nonreusable supply, not rental-type item (§ 1861(n) of the Act).
Pulse Tachometer	Deny—not reasonable or necessary for monitoring pulse of homebound patient with or without a cardiac pacemaker.
Quad-Canes	(See Walkers.)
Raised Toilet Seats	Deny—Convenience item; hygienic equipment; not primarily medical in nature (§ 1861(n) of the Act).
Reflectance Colorimeters	(See Blood Glucose Analyzers.)
Respirators	(See Ventilators.)
Rolling Chairs	Covered if the contractor's medical staff determines that the patient's condition is such that there is a medical need for this item and it has been prescribed by the patient's physician in lieu of a wheelchair. Coverage is limited to those rollabout chairs having casters of at least 5 inches in diameter and specifically designed to meet the needs of ill, injured, or otherwise impaired individuals. Coverage is denied for the wide range of chairs with smaller casters as are found in general use in homes, offices, and institutions for many purposes not related to the care or treatment of ill or injured persons. This type is not primarily medical in nature. (§ 1861(n) of the Act).
Safety Roller	(See § 60–15.)
Sauna Baths	Deny—not primarily medical in nature; personal comfort items (§§ 1861(n) and (1862(a)(6) of the Act).
Seat Lift	Covered under the conditions specified in § 60–8. Refer all to medical staff for this determination.
Self-Contained Pacemaker Monitor	Covered when prescribed by a physician for a patient with a cardiac pacemaker (see §§50–1C and 60–7).
Sitz Bath	Covered if the contractor's medical staff determines patient has an infection or injury of the perineal area and the item has been prescribed by the patient's physician as a part of his planned regimen of treatment in the patient's home.
Spare Tanks of Oxygen	Deny—convenience or precautionary supply.
Speech Teaching Machine	Deny—education equipment; not primarily medical in nature (§ 1861(n) of the Act).
Stairway Elevators	Deny—(See Elevators.) (§ 1861(n) of the Act).
Standing Table	Deny—convenience item; not primarily medical in nature (§ 1861(n) of the Act).
Steam Packs	These packs are covered under the same conditions as a heating pad (See Heating Pads.)
Suction Machine	Covered if the contractor's medical staff determines that the machine specified in the claim is medically required and appropriate for home use without technical or professional supervision.
Support Hose	Deny (See Fabric Supports). (§ 1861(n) of the Act.)
Surgical Leggings	Deny—nonreusable supply; not rental-type item (§ 1861(n) of the Act).
Telephone Alert Sytems	Deny—these are emergency communications systems and do not serve a diagnostic or therapeutic purpose.
Telephone Arms	Deny—convenience item; not medical in nature (§ 1861(n) of the Act).
Toilet Seats	Deny—not medical equipment (§ 1861(n) of the Act).

DURABLE MEDICAL EQUIPMENT REFERENCE LIST—Continued

Item	Coverage Status
Traction Equipment	Covered if patient has orthopedic impairment requiring traction equipment which prevents ambulation during the period of use (Consider covering devices usable during ambulation; e.g., cervical traction collar, under the brace provision).
Trapeze Bars	Covered if patient is bed confined and the patient needs a trapeze bar to sit up because of respiratory condition, to change body position for other medical reasons, or to get in and out of bed.
Treadmill Exercise	Deny—exercise equipment; not primarily medical in nature (§ 1861(n) of the Act).
Ultraviolet Cabinet	Covered for selected patients with generalized intractable psoriasis. Using appropriate consultation, the contractor should determine whether medical and other factors justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital.
Urinals (autoclavable hospital type)	Covered if patient is bed confined.
Vaporizers	Covered if patient has a respiratory illness.
Ventilators	Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive and negative pressure types.
Walkers	Covered if patient's condition impairs ambulation (See § 60–15).
Water and Pressure Pads and Mattresses	(See Alternating Pressure Pads and Mattresses.)
Wheelchairs	Covered if patient's condition is such that without the use of a wheelchair he would otherwise be bed or chair confined. An individual may qualify for a wheelchair and still be considered bed confined.
Wheelchairs (power operated) and wheelchairs with other special features.	Covered if patient's condition is such that a wheelchair is medically necessary and the patient is unable to operate the wheelchair manually. Any claim involving a power wheelchair or a wheelchair with other special features should be referred for medical consultation since payment for the special features is limited to those which are medically required because of the patient's condition. (See § 60–5 for power operated and § 60–6 for specially sized wheelchairs.) *Note:* A power-operated vehicle that may appropriately be used as a wheelchair can be covered. (See § 60–5 for coverage details.)
Whirlpool Bath Equipment	Covered if patient is homebound and has a condition for which the whirlpool bath can be expected to provide substantial therapeutic benefit justifying its cost. Where patient is not homebound but has such a condition, payment is restricted to the cost of providing the services elsewhere, e.g., an outpatient department of a participating hospital, if that alternative is less costly. In all cases, refer claim to medical staff for a determination.
Whirlpool Pumps	Deny—(See Portable Whirlpool Pumps.)
White Cane	Deny—(See § 60–3.)

60–11 HOME BLOOD GLUCOSE MONITORS

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

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

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

- The patient must be an insulin-treated diabetic;
- There must be documentation by a physician of poor diabetic control, i.e.,
  - —widely fluctuating blood sugars before meal time;
  - —frequent episodes of insulin reactions; or
  - —evidence of frequent significant ketosis;
- The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible family member can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and
- The device is designed for home rather than clinical use.

The following devices are covered on or after December 26, 1984.

There is also a blood glucose monitoring system designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors described above. They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable the visually-impaired to use the equipment without assistance.

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

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

The additional features and equipment of these special systems justify a higher reimbursement amount

than allowed for standard blood glucose monitors. Separately identify claims for such devices and establish a separate reimbursement amount for them. For those carriers using HCPCS, the procedure code and definition is: EO609—Blood Glucose Monitor—with special features (e.g., voice synthesizers, automatic timer, etc.).

60–14 INFUSION PUMPS

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

A. *External Infusion Pumps.*

(Effective for services performed on or after 9/26/84.)

1. *Iron Poisoning*—When used in the administration of deferozamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

2. *Thromboembolic Disease*—When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

(NOTE: For end-state renal disease patients, see 60–1.)

(Effective for services performed on or after 1/29/85.)

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

(Effective for services performed on or after 4/22/85.)

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

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

B. *Implantable Infusion Pumps.*

(Effective for services performed on or after 9/26/84.)

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

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

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

A. *External Infusion Pumps*

(Effective for services performed on or after 1/29/85.)

Diabetes—The use of an external infusion pump for the subcutaneous infusion of insulin in the treatment of diabetes is not covered.

B. *Implantable Infusion Pump*

(Effective for services performed on or after 9/26/84.)

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

Other uses of the implanted infusion pump are currently under investigation by the Public Health Service and would still be considered experimental, and therefore not covered under Medicare.

60–15 SAFETY ROLLER

(Effective for claims adjudicated on or after 6/3/85.)

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

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

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

In the case of patients with medical documentation showing severe neurological disorders or restricted use of one hand which makes it impossible for them to use a wheeled walker that does not have a sophisticated braking system, a reasonable charge for the safety roller may be determined without relating it to the reasonable charge for a standard wheeled walker. (Such reasonable charge should be developed in accordance with the instructions in Medicare Carriers Manual §§ 5010 and 5205.)

Cross Refer: Carriers Manual §§ 2100ff., § 60–9.

60–16 LYMPHEDEMA PUMPS.

Non-segmental lymphedema pumps are currently covered under the Medicare program. Effective for services rendered on or after September 19, 1986 segmental lymphedema pumps will also become a covered Medicare item.

Lymphedema is the swelling of subcutaneous tissues in an affected body part due to the accumulation of excessive lymph fluid. It is a relatively uncommon, chronic condition which may be due to many causes; e.g., surgical removal of lymph nodes, post-radiation fibrosis, scarring of lymphatic channels onset of puberty (Milroy's Disease), congenital anomalies, etc.

Both the segmental and non-segmental type pumps are appropriate for use in the home for the treatment of intractable lymphedema of the extremities. However, they may be covered only as a prescription item with appropriate physician oversight; i.e., physician evaluation of the patient's condition to determine medical necessity of the device, and suitable instruction in the operation of the machine as to the pressure to be used and the frequency and duration of use.

Cross Refer: § 60–9.

60–17 CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

(Effective for Claims Adjudicated on and After January 12, 1987.)

CPAP is a non-invasive technique for providing low levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA). The diagnosis of OSA requires documentation of at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6–7 hours of recorded sleep. The use of CPAP is covered under

Medicare when used in adult patients with moderate or severe OSA for whom surgery is a likely alternative to CPAP.

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

A diagnosis of moderate or severe obstructive sleep apnea, and

Surgery is a likely alternative.

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

Cross Refer: § 60–9.

60–18 HOSPITAL BEDS

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

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

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

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

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

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

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

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

Cross refer: Carriers Manual, § 5015.4.

65 PROSTHETIC DEVICES

65–1 HYDROPHILIC CONTACT LENSES

Hydrophilic contact lenses are eyeglasses within the meaning of the exclusion in § 1862(a)(7) of the law and so are not covered when used in the treatment of nondiseased eyes with spherical ametrophia, refractive astigmatism, and/or corneal astigmatism. Payment may be made under the prosthetic device benefit, however, for hydrophilic contact lenses when prescribed for an aphakic patient.

Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval.

(See § 45–7 for coverage of a hydrophilic lens as a corneal bandage.)

Cross-refer: Intermediary Manual, §§ 3110.3, 3110.4, 3151, and 3157; Carriers Manual, §§ 2130, 2320; Hospital Manual, §§ 228.3, 228.4, 260.1 and 260.7.

65–2 ELECTRICAL CONTINENCE AID—NOT COVERED

An electrical continence aid is a device consisting of a plastic plug, molded into the shape of the patient's anal canal, which contains two implanted electrodes that are connected by a wire to a small portable generator. An electrical current is produced which stimulates the anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

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

65–3 SCLERAL SHELL

Scleral shell (or shield) is a catchall term for different types of hard scleral contact lenses.

A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens which covers only the central non-white area encompassing the pupil and iris. Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue.

In such a case, the device serves essentially as an artificial eye. In this situation, payment may be made for a scleral shell under § 1861(s)(8) of the law.

Scleral shells are occasionally used in combination with artifical tears in the treatment of "dry eye" of diverse etiology. Tears ordinarily dry at a rapid rate, and are continually replaced by the lacrimal gland. When the lacrimal gland fails, the half-life of artifical tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of arifical tears may be avoided. The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Cross-refer: HCFA-Pub. 13–3, §§ 3110.4, 3110.5; HCFA-Pub. 14–3, §§ 2130, 2133; HCFA-Pub. 10, §§ 210.4, 211

65–4 CAROTID SINUS NERVE STIMULATOR

Implanation of the carotid sinus nerve stimulator is indicated for relief of

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

However, the use of the carotid sinus nerve stimulator in the treatment of paroxysmal supraventricular tachycardia is considered investigational and is not in common use by the medical community. The device and related services in such cases cannot be considered as reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by § 1862(a)(1) of the law.

Cross-refer: HCFA-Pub. 13–3, § 3110.4; HCFA-Pub. 14–3, § 2130; HCFA-Pub. 10, §§ 210.4, 211

65–5 ELECTRONIC SPEECH AIDS

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-refer: HCFA-Pub. 13–3, § 3110.4; HCFA-Pub. 14–3, § 2130; HCFA-Pub. 10, § 228.4

65–6 CARDIAC PACEMAKERS

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the conditions and limitations described in this section. While cardiac pacemakers have been covered under Medicare for many years, until recently there have been no specific guidelines for their implanation other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for pacemaker implanations on or after the effective dates of this instruction are subject to the guidelines of this section.

These guidelines are based on certain assumptions regarding the clinical goals of pacemaker implantation. While some uses of pacemakers represent relatively certain or unambiguous usage, many others require considerable expertise and judgment.

Consequently, the medical necessity for pacemaker implantation must be viewed in the context of the overall management of the particular patient. The appropriateness of such implants may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemakers are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which pacemaker implantation may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of pacemaker implants can be expected to change, and instructions modified as more information becomes available.

It should be noted that this instruction applies only to permanent, implanted pacemakers, and does not address the use of temporary, nonimplanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacemaker implants for patients in general. These are intended as guidelines for Medicare contractors to use in assessing the medical necessity of claims for pacemaker implantation. As with other guidelines, final coverage determinations must take account of the circumstances of the particular claim, as well as factors such as the medical history of the individual patient. However, as a general rule, contractors may view the two groups of current medical concepts below as representing:

Group I: Single-Chamber Cardiac Pacemakers—(A) conditions under which single-chamber pacemaker claims may be considered covered without further claims development; and (B) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

Group II. Dual-Chamber Cardiac Pacemakers—(A) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and (B) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single-and dual chamber pacemakers, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

GROUP I: SINGLE-CHAMBER CARDIAC PACEMAKERS—Effective for services rendered on or after March 16, 1983.

A. *COVERED.*

Conditions under which implantation of a cardiac pacemaker is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third degree) AV heart block.

2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.

3. Second degree AV heart block of Type II (i.e., *no* progressive prolongation of P–R interval prior to each blocked beat).

4. Second degree AV heart block of Type I (i.e., progressive prolongation of P–R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.

5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50–59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

7. Sinus bradycardia which is the consequence of long-term necessary drug treatment for which there is no acceptable alternative, when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable

to the bradycardia rather than to some other cause.

8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block—i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest—when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.

13. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Mobitz Type II second degree AV block in association with bundle branch block.

14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

Effective for services rendered on or after May 9, 1985.

15. Second degree AV heart block of Type I with the QRS complexes prolonged.

B. *NOT COVERED*—Additional claims development may be required.

Conditions which, although used by some physicians as bases for permanent pacemaker implantation, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of indications cited above. Contractors should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim. The object of such further development is to establish whether the particular claim actually meets the conditions in A. above. In claims where this is not the case or where such an event appears unlikely, the contractor may deny the claim.

1. Syncope of undetermined cause.

2. Sinus bradycardia without significant symptoms.

3. Sino-atrial block or sinus arrest without significant symptoms.

4. Prolonged R–R intervals with atrial fibrillation (without third degree AV block) or with other causes of transient ventricular pause.

5. Bradycardia during sleep.

6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.

7. Asymptomatic second degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle.

GROUP II. DUAL-CHAMBER CARDIA PACEMAKERS—Effective for services rendered on or after May 9, 1985.

A. *COVERED.*

Conditions under which implantation of a dual-chamber cardiac pacemaker is considered acceptable or necessary in the general medical community unless conditions #1 and #2, Group II.B., are present:

1. Patients in whom single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.

2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.

3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with congestive heart failure despite adequate other medical measures.

4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the conditions, as listed in Group I.A. (Single-Chamber Cardia Pacemakers), if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. *NOT COVERED.*

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions—e.g., chronic atrial fibrillation or flutter, or giant left atrium.

2. Frequent or persistent supraventricular tachycardias, *except* where the pacemaker is specifically for the control of the tachycardia.

3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Type II second degree AV block in association with bundle branch block.

Cross refer: HCFA Pub. 13–3, §§ 3101.4, 3110.4, HCFA Pub. 14–3, § 2130; HCFA Pub. 10, §§ 210.4, 228.4.

65–7 INTRAOCULAR LENSES (IOL's)

An intraocular lens, or pseudophakos, is a hard artificial lens which may be implanted to replace the natural lens after cataract surgery. Intraocular lens implantation services, as well as the lens itself, may be covered if reasonable and necessary for the individual. Implantation services may include hospital, surgical, and other medical services, including pre-implantation ultrasound (A-scan) eye measurement of one or both eyes.

The Food and Drug Administration (FDA) has classified IOL's into the following four categories, any of which may be covered:

- Anterior chamber angle fixation lenses;
- Iris fixation lenses;
- Irido-capsular fixation lenses; and
- Posterior chamber lenses

Although the FDA still considers IOL's investigational, their coverage under Medicare is an exception to the general policy not to cover experimental or investigational items or services. The exception is made because the Congress, recognizing the widespread

use of IOL's, directed the FDA to study them without interfering with their availability to patients.

Cross-refer: HCFA-Pub. 13-3, §§ 3110.4, 3151, 3157; HCFA-Pub. 14-3; § 2130; HCFA-Pub. 10, § 228.4

65-8 ELECTRICAL NERVE STIMULATORS

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

A. *Peripheral Nerve Stimulators.*—Payment may be made under the prosthetic devices benefit for the following types of peripheral nerve stimulators:

1. *Transcutaneous Electrical Nerve Stimulator (TENS).*—This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings—in the patient's home, a physican's office, or in an outpatient clinic. (See § 45-25 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

2. *Implanted Peripheral Nerve Stimulator.*—Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater then ½ inch. Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in § 35-46 such use of the stimulator would be covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. *Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators).*—The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. *Types of Implantations.*—There are two types of implantations covered by this instruction:

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

b. *Depth Brain Neurostimulation.*—The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter).

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

a. The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;

b. With respect to a., other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;

c. Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);

d. All the facilities, equipment and professional and support personnel required for the proper diagnosis, treatment training and followup of the patient (including that required to satisfy condition c.), must be available; and

e. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Contractors may find it helpful to work with PSROs to obtain the information needed to apply these conditions to claims.

Cross-refer: HCFA Pub. 13-3, § 3110.4; §§ 35-20, 35-27

65-9 MECHANICAL/HYDRAULIC INCONTINENCE CONTROL DEVICES

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

Implantable electronic stimulators continue to be not covered. See Section 65-11 (Bladder Stimulators (Pacemakers)).

Cross-refer: HCFA Pub. 13-3, § 3110.4.

65-10 ENTERAL AND PARENTERAL NUTRITIONAL THERAPY COVERED AS A PROSTHETIC DEVICE (Effective for items and services furnished on and after 07-11-84.)

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision, which requires that the patient must have a permanently inoperative internal body organ or function thereof (see 3110.4). Therefore, enteral and parenteral nutritional therapy is not covered under Part B in situations involving temporary impairments. Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence will be considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and § 3110.4.

65-10.1 *Parenteral Nutrition Therapy.*—Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the supeiror vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be reimbursed for their services, nor is

reimbursement available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription, and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that would typically qualify for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than 3 months by the carrier's medical consultant or specially trained staff, relying on such medical and other documentation as the carrier may require. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program reimbursement for the pump will be based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation (see § 3113.2B).

Nutrient solutions for parenteral therapy are routinely covered. However Medicare will pay for no more than one months supply of nutrients at any one time. Reimbursement for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive pre-mixed solutions only under the latter circumstances.

65–10.2 *Enteral Nutrition Therapy.*—Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes, and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be reimbursed for their services, nor is reimbursement available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

Typical examples of conditions that would qualify for coverage are head and neck cancer with reconstructive surgery, and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription, and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician, etc.) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the contractor's medical consultant or specially trained staff, and additional medical documentation considered necessary should be obtained as part of this review.

Medicare will pay for no more than one months supply of enteral nutrients at any one time.

If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome, etc. Program reimbursement for the pump will be based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation (see §§ 3113.2).

65–10.3 *Nutritional Supplementation.*—Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

65–11 BLADDER STIMULATORS (PACEMAKERS)—NOT COVERED

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

The use of spinal cord electrical stimulators, rectal electrical stimulators (including the Continaid), and bladder wall stimulators (including the Mentor Bladder Pacemaker) cannot be considered reasonable and necessary. Therefore, no program payment may be made for these devices or for their implantation.

65–13 PHRENIC NERVE STIMULATOR

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

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

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

65–14 COCHLEAR IMPLANTATION

(Effective for services performed on and after October 1, 1986.)

As cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture and amplify sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide an awareness and identification of sounds and to facilitate communication for persons who are profoundly hearing impaired.

Medicare coverage is provided only for those patients who meet *all* of the following selection guidelines:

1. Diagnosis of total sensorineural deafness that cannot be mitigated by use of a hearing aid in patients whose auditory cranial nerves are stimulable.

2. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.

3. Post-lingual deafness.

4. Adulthood (at least 18 years of age).

5. Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system.

6. No contraindications to surgery.

65–15 ARTIFICIAL HEARTS AND RELATED DEVICES—NOT COVERED

There are several devices either in use or under development which replace all or part of the human heart, or assist the heart in performing its pumping function. Artificial hearts are considered investigational and not covered under Medicare either when used as a permanent replacement for a human heart, or when used as temporary life-support systems (i.e., until a human heart becomes available for transplant).

Also, ventricular assist devices used as temporary life-support systems are also considered investigational and not covered under the Medicare program.

65–16 TRACHEOSTOMY SPEAKING VALVE

A trachea tube has been determined to satisfy the definition of a prosthetic device, and the tracheostomy speaking valve is an "add on" to the trachea tube which may be considered a medically necessary accessory that enhances the function of the tube. In other words it makes the system a better prothesis. As such, a tracheostomy speaking valve is covered as an element of the trachea tube which makes the tube more effective.

70 BRACES—TRUSSES—ARTIFICIAL LIMBS AND EYES

70–1 CORSET USED AS A HERNIA SUPPORT

A hernia support (whether in the form of a corset or truss) which meets the definition of a brace is covered under Part B under § 1861(s)(9) of the law.

Cross-refer: Intermediary Manual, § 3110.5; Carriers Manual, § 2133; Hospital Manual, § 228.5

70–2 SYKES HERNIA CONTROL

Based on professional advice it has been determined that the Sykes Hernia Control (a spring-type, "U-shaped," strapless truss) is not functionally more beneficial than a conventional truss. Make program reimbursement for this device only when an ordinary truss would be covered. (Like all trusses, it is only of benefit when dealing with a reducible hernia). Thus, where a charge for this item is substantially in excess of that which would be reasonable for a conventional truss used for the same condition, base reimbursement on the reasonable charges for the conventional truss.

Cross-refer: Intermediary Manual, § 3110.5; Carriers Manual, § 2133; Hospital Manual, § 228.5

70–3 PROSTHETIC SHOE

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

Cross-refer: Intermediary Manual, § 3110.5; Carriers Manual, § 2133; Hospital Manual, § 228.5

80 PATIENT EDUCATION PROGRAMS

81–1 INSTITUTIONAL AND HOME CARE PATIENT EDUCATION PROGRAMS

While the law does not specifically identify patient education programs as covered services, reimbursement may be made under Medicare for such programs furnished by providers of services (i.e., hospitals, SNFs, HHAs, and OPT providers) to the extent that the programs are appropriate, integral parts in the rendition of covered services which are reasonable and necessary for the treatment of the individual's illness or injury. For example, educational activities carried out by nurses-teaching patients to give themselves injections, follow prescribed diets, administer colostomy care, administer medical gases, and carry out other inpatient care activities—may be reimbursable as a part of covered routine nursing care. Also, the teaching by an occupational therapist of compensatory techniques to improve a patient's level of independence in the activities of daily living may be reimbursed as a part of covered occupational therapy. Similarly, the instruction of a patient in the carrying out of a maintenance program designed for him by a physical therapist may be reimbursed as part of covered physical therapy.

However, where the educational activities are not closely related to the care and treatment of the patient, such as programs directed toward instructing patients or the public generally in preventive health care activities, reimbursement cannot be made since the law limits Medicare payment to covered care which is reasonable and necessary for the treatment of an illness or injury. For example, programs designed to prevent illness by instructing the general public in the importance of good nutritional habits, exercise regimens, and good hygiene are not reimbursable under the program.

90 NURSING SERVICES

90–1 HOME HEALTH VISITS TO A BLIND DIABETIC

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

To qualify for home health benefits, a blind diabetic must be confined to his home, under the care of a physician, and

a need of either skilled nursing services on an intermittent basis or physical therapy or speech therapy. Effective July 1, 1981, a person may qualify for home health benefits based on his or her need for skilled nursing services on an intermittent basis, physical therapy, speech therapy, or occupational therapy. Effective December 1, 1981, occupational therapy is eliminated as a basis for entitlement to home health services. However, if a person has otherwise qualified for home health services because of the need for skilled nursing care, physical therapy or speech therapy, the patient's eligibility for home health services may be extended solely on the basis of the continuing need for occupational therapy. (See Intermediary Manual, § 3116; Home Health Agency Manual, § 203; Hospital Manual, § 155.3.) There must be a plan of treatment, established and periodically reviewed by a physician, which indicates that there is a recurring need for home health services to supplement the physician's contacts with the patient; e.g., skilled nursing visits for observing and determining the need for changes in the level and type of care which has been prescribed. (See Intermediary Manual, § 3117ff; Home Health Agency Manual, § 204ff.) Once an initial regimen has been established, the frequency of need for further home health services can vary greatly from patient to patient, depending on their condition and the likelihood of its changing. Some may need visits only every 90 days, for example, while others may require them much more frequently. If a nurse makes a visit to provide skilled services, and also prefills syringes, the purpose of the visit, which was to provide skilled services, does not change. However, if the sole purpose of the nurse's visit is to prefil insulin syringes for a blind diabetic, it is not a skilled nursing visit although it may be reimbursed as such as indicated below.

Filling a syringe can be safely and effectively performed by the average nonmedical person without the direct supervision of a licensed nurse. Consequently, it would not constitute a skilled nursing service even if it is performed by a nurse. (See Intermediary Manual, § 3117.2B; Home Health Agency Manual, § 204.2B.) The personal care duties normally performed by home health aides include assisting the patient with medications ordered by a physician which are ordinarily self-administered. (See Intermediary Manual, § 3119.2; Home Health Agency Manual, § 206.2.) Performance of such a service by an aide is consistent with the Medicare conditions of participation for home health agencies. Therefore, home health aide services would be appropriate for those blind diabetics who are qualified for home health benefits and who cannot fill their syringes. An adequately trained home health aide could make intermittent visits, usually on a weekly basis, to the home for the purpose of filling that supply of insulin ordered by the physician.

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

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

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

Cross-refer: Intermediary Manual, §§ 3116, 3117.2B, 3117ff, 3119.2; Home Health Agency Manual, §§ 203, 204ff, 204.2B, 206.

90-2 HOME HEALTH NURSES' VISITS TO PATIENTS REQUIRING HEPARIN INJECTIONS

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

Medicare payment may be made for several visits by the home health nurse to teach the patient or the caring person to give subcutaneous injections of low dose heparin if it is prescribed by a physician for a homebound patient who: (1) is pregnant and requires anticoagulant therapy, or (2) requires treatment for deep venous thrombosis or pulmonary emboli or for another condition requiring anticoagulation and documentation justifies that the patient cannot tolerate warfarin. If the patient or caring person is unable to administer the injection, nursing visits to give the injections on a daily basis, 7 days a week, for a period of up to 6 months (in the case of pregnancy, visits may be made for a period beyond 6 months if reasonable and necessary) would be reimbursed by Medicare. Coverage for these services after 6 months of treatment would be provided only if the prescribing physician can justify and document the need for such an extended course of treatment. Documentation of need for heparin injections beyond 6 months would not be required for pregnant patients who meet the homebound criteria.

Cross-refer: Intermediary Manual, §§ 3117.4B, 31174H.1; Home Health Agency Manual, §§ 204.4B, 204.4H.1.

[FR Doc. 89-19426 Filed 8-18-89; 8:45 am]
BILLING CODE 4160-15-M

Privacy Act of 1974; System of Records

AGENCY: Health Care Financing Administration (HCFA), Department of Health and Human Services (HHS).

ACTION: Notice of New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, "Drug Bill Processor Records on Medicare Prescription Drug Beneficiaries," HHS/HCFA/BPO No. 09-70-0528. We have provided background information about the proposed system in the "Supplementary Information" section below. Although the Privacy Act requires that only the "routine uses" portion of the system be published for comment, HCFA invites comments on all portions of this notice.

DATES: HCFA filed a new system report with the Chairman of the Committee on Government Operations of the House of Representatives, the Chairman of the Committee on Governmental Affairs of the Senate, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on August 16, 1989. The new system of records, including routine uses, will become effective October 20, 1989, unless HCFA receives comments which warrant modification of the notice.

ADDRESS: The public should address comments to Richard A. DeMeo, HCFA Privacy Act Officer, Office of Budget and Administration, Health Care Financing Administration, Room G-M-1, East Low Rise, 6325 Security Boulevard, Baltimore, Maryland 21207. Comments received will be available for inspection at this location.

FOR FURTHER INFORMATION CONTACT: Dorothy A. Kielkopf, Division of Operational Systems Development, Office of Program Operations Procedures, Bureau of Program Operations, Health Care Financing Administration, Room G-A-1, Meadows East Building, 6325 Security Boulevard, Baltimore, Maryland 21207. Telephone (301) 966-6121.

SUPPLEMENTARY INFORMATION: HCFA proposes to initiate a new system of records and to collect data under the authority of section 1842(o)(4) of the Social Security Act as amended by the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100-360), which mandates that: "the Secretary shall establish, by not later than January 1, 1991, a point-of-sale electronic system for use by carriers and participating pharmacies in the submission of information respecting covered outpatient drugs dispensed to Medicare beneficiaries under this part." (Related provisions of the Social Security Act are at sections 1842(b)(3)(J) and (K), 1842(c)(1)(A)(ii), 1842(f)(3), 1842(h)(1), and the remainder of Section 1842(o). This system of records will contain beneficiary-specific information on Medicare prescription drug benefit entitlement, deductible status, and, over time, prescription drug use. HCFA will thus be able to properly and expeditiously pay Medicare benefits to or on behalf of the beneficiary in question and to inform the beneficiary at the point of sale of her/his deductible status and of potential prescription drug interaction problems. Under all conditions, sensitive data will be safeguarded from disclosure and protected from unauthorized modification or destruction. Each user will be required to present a valid password before being allowed access to the system. Only those persons whose duties require access to beneficiaries' records will be given passwords. Authorized pharmacy personnel will have only limited read/write access to beneficiaries' records. Beneficiary-specific prescription Drug information will be available to authorized personnel of enrolled pharmacies only in instances of potential outpatient prescription drug interactions, and the information available will be limited to the prescription drug(s) implicated.

The Privacy Act permits us to disclose information without the consent of the individual for "routine uses"—that is, disclosure for purposes that are compatible with the purpose for which we collect the information. We anticipate that disclosure under the routine uses will not result in any unwarranted adverse effects on personal privacy.

Dated: August 14, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.