45 SUPPLIES--DRUGS

45-1 L-DOPA

A. Part A Payment 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 §1861(t) of the Act; i.e., on its inclusion in the compendia named in the Act or approval by the hospital's pharmacy and drug therapeutics (P&DT) or equivalent committee. (Levodopa (L-Dopa) has been favorably evaluated for the treatment of Parkinsonism by A.M.A. Drug Evaluations, First Edition 1971, the replacement compendia for "New Drugs.")

Inpatient hospital services are frequently not required in many cases when L-Dopa therapy is initiated. Therefore, determine the medical need for inpatient hospital services on the basis of medical facts in the individual case. It is not necessary to hospitalize the typical, well-functioning, ambulatory Parkinsonian patient who has no concurrent disease at the start of L-Dopa treatment. It is reasonable to provide inpatient hospital services for Parkinsonian patients with concurrent diseases, particularly of the cardiovascular, gastrointestinal, and neuropsychiatric systems. Although many patients require hospitalization for a period of under 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/her, physical therapy services required to enable him/her to achieve this goal are payable provided they require the skills of a qualified physical therapist and are furnished by or under the supervision of such a therapist. However, once the individual's restoration potential has been achieved, the services required to maintain him/her at this level do not generally require the skills of a qualified physical therapist. In such situations, the role of the therapist is to evaluate the patient's needs in consultation with his/her physician and design a program of exercise appropriate to the capacity and tolerance of the patient and treatment objectives of the physician, leaving to others the actual carrying out of the program. While the evaluative services rendered by a qualified physical therapist are payable as physical therapy, services furnished by others in connection with the carrying out of the maintenance program established by the therapist are not.

See Intermediary Manual, §3101.3 and 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 for inpatient services, the role of physical therapy, and the use of laboratory tests. (See subsection A.)

Where inpatient care is required and L-Dopa therapy is initiated in the SNF, limit the stay to a maximum of 4 weeks; but in many cases the need may be 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.

See 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; and Hospital Manual, §230.4B.) However, physician services rendered in connection with its administration and control of its side effects are covered if determined to be reasonable and necessary. Initiation of L-Dopa therapy on an outpatient basis is possible in most cases. Visit frequency ranging from every week to every 2 or 3 months is acceptable. However, after half a year of therapy, visits more frequent than every month would usually not be reasonable.

45-3 INSULIN SYRINGE

Medical supplies are covered under §1861(s)(2)(A) of the Act 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/her 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 §l861(s)(2)(A) of the Act.

See Intermediary Manual, §3112.4B and Carriers Manual, §2050.

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

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

See Intermediary Manual, §§3101.3 and 3158 and Carriers Manual, §§2050.5 and 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, corneal edema, descemetocele, corneal ectasis, Mooren's ulcer, anterior corneal dystrophy, neurotrophic keratoconjunctivitis, and for other therapeutic reasons.

Payment may be made under §1861(s)(2) of the Act for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician's service. Payment for the lens is included in the payment for the physician's service to which the lens is incident. 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.)

See Intermediary Manual, §3112.4 and Carriers Manual, §§2050.1 and 15010.

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 Act 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.l, 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.l, 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 §l861(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 Divison of Cancer Treatment only if the following requirements are met:

- o A physician must be registered with the NCI as an investigator by having completed an FD-Form 1573;

- o A written request for the drug, indicating the disease to be treated, must be submitted to the NCI;

- o The use of the drug must be limited to indications outlined in the NCIs guidelines; and

- o 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^3 whole blood. Accepted indications for granulocyte transfusions include:

- Granulocytopenia with evidence of gram negative sepsis; and

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

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 of acute pain resulting 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 cases 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 durable medical equipment as described in §60-20.

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 viewed as adjunctive to traditional immunosuppressive products such as steroids and anti-metabolic drugs. At present, lymphocyte immune globulin preparations are not recommended to replace conventional immunosuppressive drugs, but to supplement them and to be used as alternatives to elevated or accelerated dosing with conventional immunosuppressive agents.

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

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 determined that the only purpose for which DMSO is safe and effective for humans is in the treatment of the bladder condition, interstitial cystitis. Therefore, the use of DMSO for all other indications is not considered to be reasonable and necessary. Payment may be made for its use only when reasonable and necessary for a patient in the treatment of interstitial cystitis.

45-24 ANTI-INHIBITOR COAGULANT COMPLEX (AICC)

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

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:

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

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

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

- o 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;

- o 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;

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

- o 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

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

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

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

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

(See conditions for coverage of the use of TENS in the diagnosis and treatment of chronic intractable pain in §§35-46 and 60-20 and the use of NMES in the treatment of disuse atrophy in §35-77.)

45-26 PLATELET-DERIVED WOUND HEALING FORMULA--NOT COVERED

A platelet-derived formula containing growth factors intended to treat nonhealing wounds (e.g., Procuren) is provided through hospital-based outpatient facilities as part of comprehensive wound-care programs designed to treat patients with chronic nonhealing wounds. It is usually applied at first in the presence of a physician, with the patient continuing applications at home. There is a lack of sufficient published data to determine the safety and efficacy of the platelet-derived wound healing formula (based on a technology review by the Public Health Service). Therefore, it is not covered under Medicare because it is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

45-27 BLOOD TRANSFUSIONS

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

A. Definitions.--

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

2. Autologous Blood Transfusion.--An autologous blood transfusion is the precollection and subsequent infusion of a patient's own blood.

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

4. Perioperative Blood Salvage.--Perioperative blood salvage is the collection and reinfusion of blood lost during and immediately after surgery.

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

1. Hospital Part A and B Coverage and Payment.--Under §1862(a)(14) of the Act, nonphysician services furnished to hospital patients are covered and paid for as hospital services. The inclusion of services provided to hospital patients by an outside supplier as part of hospital services is referred to as "bundling." In a situation where a hospital obtains either autologous or donor-directed blood from an independent supplier, the supplier collects, processes, and stores the blood and, typically, delivers it to the hospital. The hospital is responsible for paying the supplier.

Part A payment, as specified in §1814(b) of the Act, and Part B payment, as specified in §1833(a) of the Act, relate to reasonable cost as defined in §1861(v) of the Act. Under this system, when a hospital obtains autologous or donor-directed blood from an independent blood bank, Medicare recognizes only a processing fee charged to the hospital by the independent blood bank because the blood has been replaced, albeit in advance. The processing fee is recorded by the hospital in the blood storing, processing, and transfusion cost center. This cost center also includes any costs the hospital itself incurs to process and administer the blood after it has been procured. This includes the cost of such activities as storing, type crossmatching, and transfusing the blood, as well as the cost of spoiled or defective blood. The hospital may generate a charge for these costs (except for spoiled or defective blood) and, under cost reimbursement, Medicare picks up its share of the costs through cost apportionment. As provided in §1886 of the Act, under the prospective payment system (PPS), the diagnosis related group (DRG) payment to the hospital includes all covered blood and blood processing expenses, whether or not the blood is eventually used.

In a situation where the hospital operates its own blood collection activities, rather than using an independent blood supplier, the costs incurred to collect autologous or donor-directed blood are recorded in the whole blood and packed red blood cells cost center. Because the blood has been replaced, Medicare does not recognize a charge for the blood itself. Therefore, under cost reimbursement, these costs are shared by all patients through cost apportionment. The costs incurred by the hospital to store, process, and transfuse the blood, as well as the cost of spoiled or defective blood, are recorded in the blood storing, processing, and transfusion cost center. The hospital may generate a charge for these costs (except for the cost of spoiled or defective blood) and, under cost reimbursement, Medicare picks up its share of these costs through cost apportionment. Under PPS, the DRG payment is intended to pay for all covered blood and blood services, whether or not the blood is eventually used.

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

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

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

45-28 ANTIGENS PREPARED FOR SUBLINGUAL ADMINISTRATION

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

45-29 INTRAVENOUS IRON THERAPY (effective for services performed on or after12/01/00)

Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing hemodialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) which transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hemocrit levels. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. Body iron stores can be supplemented with either oral or intravenous (IV) iron products.

The evidence suggests that there is little to distinguish various forms of IV iron therapy in terms of effectiveness. Rather, the medical literature indicates that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia. Review of medical literature indicated that the distinction among IV iron products lies within their safety profiles. The IV iron dextran products are associated with a small incidence of severe, life-threatening anaphylaxis. These type I hypersensitivity reactions, which are not dose-related, are immunoglobulin (Ig) E-mediated and are apparently exclusively associated with the dextran forms of injectable iron. In fact, clinical evidence indicates that the dextran component itself is what triggers the severe, life-threatening anaphylactic reactions. *Sodium ferric gluconate complex in sucrose injection* has demonstrated no life-threatening anaphylaxis and a less severe adverse-reaction rate when compared to iron dextran products. Therefore, effective December 1, 2000, Medicare covers *sodium ferric gluconate complex in sucrose injection* when used as a first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy.

45-30 PHOTOSENSITIVE DRUGS

Photosensitive drugs are the light-sensitive agents used in photodynamic therapy. Once introduced into the body, these drugs selectively identify and adhere to diseased tissue. The drugs remain inactive until they are exposed to a specific wavelength of light, by means of a laser, that corresponds to their absorption peak. The activation of a photosensitive drug results in a photochemical reaction which treats the diseased tissue without affecting surrounding normal tissue.

Verteporfin

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. This drug was first approved by the Food and Drug Administration (FDA) on April 12, 2000, and subsequently, approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug as defined under §1861(t)(1) of the Social Security Act. Effective July 1, 2001, Verteporfin (Q3013 – Injection, Verteporfin, 15 mg) is only covered when used in conjunction with ocular photodynamic therapy (see §35-100 PHOTODYNAMIC THERAPY) when furnished intravenously incident to a physician's service. For patients with age-related macular degeneration, Verteporfin is only covered with a diagnosis of neovascular age-related macular degeneration (ICD-9-CM 362.52) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (CPT code 92235). Subsequent follow-up visits will require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of retreatments.