MEDICARE PART A BULLETIN

March 5, 1997 General Medicare Bulletin G-276

TO: All Medicare Providers

FROM: Andy DePirro, Director, Program Relations

SUBJECT: **VARIOUS COVERAGE ISSUES HCFA-PUBLICATION 6: SECTIONS 35-20, 35-48, 35-94, 35-95, 35-96, 35-97, 60-14 and 65-7.**

ATTENTION MEDICARE BUSINESS OFFICE MANAGER: Please distribute to all appropriate health care facility personnel.

The Health Care Financing Administration (HCFA) published these coverage clarifications and/or new implementing instructions, via the Medicare Coverage Issues Manual (HCFA-Publication 6), Transmittals 92 and 93. Even though these instructions were issued to providers via the HCFA manual revision process, the purpose of this bulletin is to ensure providers are aware of these Medicare coverage issue regulations.

Section 35-20, Treatment of Motor Function Disorders with Electric Nerve Stimulation- Effective for Services On and After April 3, 1997

This section is revised to reflect that the present instruction relating to electrical nerve stimulation does not apply to deep brain stimulation provided by an implanted stimulator device. Therefore, deep brain stimulation provided via an implanted deep brain stimulator is subject to Medicare coverage at the discretion of the carrier.

Section 35-48, Osteogenic Stimulation: New Implementing Instruction - Effective for Services On and After April 3, 1997

This section indicates that ultrasonic osteogenic stimulators are not covered under Medicare because there is insufficient evidence to support the medical necessity of using these devices.

Section 35-94, Transmyocardial Revascularization With Laser - Not Covered- Effective for Services On and After May 19, 1997

This section indicates that Transmyocardial Revascularization (TMR) with laser is not covered. Because of the lack of scientific evidence available at this time concerning the safety and effectiveness of TMR, this procedure is not considered reasonable and necessary under §1862(a)(1)(A) of the Social Security Act.

Section 35-95, Partial Ventriculectomy (Also known as Ventricular Reduction, Ventricular Remodeling or Heart Volume Reduction Surgery) - Effective for Services On and After April 15, 1997

This section is added to explain that this procedure is not covered. Because the mortality rate is high and there are no published scientific articles or clinical studies, the procedure is not considered reasonable and necessary within §862(a)(1) of the Act.

Section 35-96, Cryosurgery of Prostate- Effective for Services On and After April 15, 1997

This section explains that cryosurgical ablation of the prostate is not covered based upon evidence which is not yet sufficient to demonstrate the effectiveness of the procedure. Therefore, it is not considered to be reasonable and necessary under §1862(a)(1)(A) of the Act.

Section 35-97, Vertebral Axial Decompression (VAX-D)- Effective for Services On and After April 15, 1997

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

Section 60-14, Infusion Pumps- Effective for Services On and After April 15, 1997

This section is amended to specify that implantable infusion pumps for the delivery of insulin to treat diabetes is not covered. The data do not demonstrate that the pump provides effective administration of insulin.

Section 65-7, Intraocular Lenses (IOLs)- Effective for Services On and After May 19, 1997

This section is being revised because the Food and Drug Administration (FDA) no longer uses the categories identified in this section to classify IOLs. Additionally, the FDA no longer has adjunct studies for IOLs. This manual revision does not represent a change in Medicare coverage of IOLs. FDA-approved IOLs continue to be covered if the reasonable and necessary requirements are not met. Refer to the Medicare Carriers Manual, §2130.

Questions regarding this bulletin may be addressed to the Medicare Part A Customer Service Department by calling (904) 355-8899.

SECTION 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 innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary.

See §§35-27 and 65-8.

NOTE: Medicare coverage of deep brain stimulation by implantation of a stimulator device is not prohibited. Therefore, coverage of deep brain stimulation provided by an implanted deep brain stimulator is at the carrier's discretion.

SECTION 35-48 OSTEOGENIC STIMULATION (EFFECTIVE FOR SERVICES PERFORMED ON AND AFTER SEPTEMBER 15, 1980.)

A. Electrical Osteogenic Stimulators: 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 issue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

1. Noninvasive Stimulator: The noninvasive stimulator device is covered only for the following indications:

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

2. Invasive (Implantable) Stimulator: The invasive stimulator device is covered only for the following indications:

- o Nonunion of long bone fractures;
- o As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple

level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1,etc).

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

B. Ultrasonic Osteogenic Stimulators: An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound, conductive, coupling gel in order to accelerate the healing time of the fracture. The device is intended for use with cast immobilization.

There is insufficient evidence to support the medical necessity of using an ultrasonic osteogenic stimulator. Therefore, the device is not covered, because it is not considered reasonable and necessary.

SECTION 35-94 TRANSMYOCARDIAL REVASCULARIZATION WITH LASER - NOT COVERED

Transmyocardial Revascularization with laser, abbreviated as **TMR**, is a surgical process whereby 15 to 30 channels are bored into the myocardium of the beating heart in an attempt to restore perfusion to areas of the heart not being reached by weakened or clogged arteries. Because of the lack of scientific evidence available concerning the safety and effectiveness of **TMR**, this procedure is not covered. When additional scientific evidence becomes available, this policy will be reevaluated.

SECTION 35-95 PARTIAL VENTRICULECTOMY (ALSO KNOWN AS VENTRICULAR REDUCTION, VENTRICULAR REMODELING, OR HEART VOLUME REDUCTION SURGERY) - NOT COVERED

Partial Ventriculectomy, also known as ventricular reduction, ventricular remodeling, or heart volume reduction surgery, was developed by a Brazilian surgeon and has been performed only on a limited basis in the United States. This procedure is performed on patients with enlarged hearts due to end-stage congestive heart failure. Partial Ventriculectomy involves reducing the size of an enlarged heart by excising a portion of the left ventricular wall followed by repair of the defect. It is asserted that this procedure makes the failing heart pump better by improving the efficiency of the remaining left ventricle.

Since the mortality rate is high and there are no published scientific articles or clinical studies regarding partial Ventriculectomy, this procedure cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act. Therefore, partial Ventriculectomy is not covered by Medicare.

SECTION 35-96 CRYOSURGERY OF PROSTATE - NOT COVERED

Cryosurgery of the prostate gland, a.k.a. cryosurgical ablation of the prostate (CSAP), destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland. The evidence is not yet sufficient to demonstrate the effectiveness of this procedure. Therefore, cryosurgery of the prostate cannot be considered reasonable and necessary under §1862(a)(1)(A) of the Social Security Act.

SECTION 35-97 VERTEBRAL AXIAL DECOMPRESSION (VAX-D) - NOT COVERED

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

SECTION 60-14 INFUSION PUMPS

THE FOLLOWING INDICATIONS FOR TREATMENT USING INFUSION PUMPS ARE COVERED UNDER MEDICARE:

A. External Infusion Pumps

1. Iron Poisoning (Effective for Services Performed On or After 9/26/84). When used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

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

3. Chemotherapy for Liver Cancer (Effective for Services Performed On or After 1/29/85). The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor.

4. Morphine for Intractable Cancer Pain (Effective for Services Performed On or After 4/22/85). Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice).

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

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

B. Implantable Infusion Pumps

1. Chemotherapy for Liver Cancer (Effective for Services Performed On or After 9/26/84). The implantable infusion pump is covered for intra-arterial infusion of 5-FUdR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable or (2) where the patient refuses surgical excision of the tumor.

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

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

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

3. Opioid Drugs for Treatment of Chronic Intractable Pain. An implantable infusion pump is covered when used to administer Opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

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

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

4. Coverage of Other Uses of Implanted Infusion Pumps. Determinations may be made on coverage of other uses of implanted infusion pumps if the contractor's medical staff verifies that:

o The drug is reasonable and necessary for the treatment of the individual patient;

o It is medically necessary that the drug be administered by an implanted infusion pump; and

o The FDA approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.

5. Implantation of Infusion Pump Is Contraindicated. The implantation of an infusion pump is contraindicated in the following patients:

o Patients with a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);

o Patients who have an infection;

o Patients whose body size is insufficient to support the weight and bulk of the device; and

o Patients with other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

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

THE FOLLOWING INDICATIONS FOR TREATMENT USING INFUSION PUMPS ARE NOT COVERED UNDER MEDICARE:

A. External Infusion Pumps

1. Diabetes (Effective for Services Performed On or After 1/29/85). The use of an external infusion pump for the subcutaneous infusion of insulin in the treatment of diabetes is not covered.

2. Vancomycin (Effective for Services Beginning On or After September 1, 1996). Medicare coverage of vancomycin as a durable medical equipment infusion pump benefit is not covered. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.

B. Implantable Infusion Pump

1. Thromboembolic Disease (Effective for Services Performed On or After 9/26/84). According to the Public Health Service, there is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump. Therefore, the

use of an implantable infusion pump for infusion of heparin in the treatment of recurrent thromboembolic disease is not covered.

2. Diabetes: Implanted infusion pumps for the infusion of insulin to treat diabetes is not covered. The data do not demonstrate that the pump provides effective administration of insulin.

SECTION 65-7 INTRAOCULAR LENSES (IOLs)

An intraocular lens, or pseudophakos, is an 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.

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