Medicare

Coverage Issues Manual

Department of Health and Human Services (DHHS)

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp.	2 pp.
Secs. 35-71 - 35-78	4 pp.	4 pp.

NEW/REVISED MATERIAL-- ***EFFECTIVE DATE: April 1, 2000***
IMPLEMENTATION DATE: April 1, 2000

Section 35-74, External Counterpulsation (ECP) for Severe Angina, is revised to eliminate the confusion generated from the coverage policy that took effect July 1, 1999. All references to the acronym EECP are deleted and replaced by ECP.

The requirement further limiting coverage to specific ECP systems, (those that have "sufficiently demonstrated their medical effectiveness in well-designed clinical trials") has been removed.

For services furnished between July 1, 1999 through December 31, 1999 use CPT code 93799. For services furnished on or after January 1, 2000 use HCPCS code G0166 until a CPT code is established.

This section of the coverage manual is a national coverage decision made under §1862(a)(1) of the Social Security Act (the Act). National coverage determinations are binding on all Medicare carriers, fiscal intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice Organizations (§1852 (a)(1)(A)) of the Act. In addition, an administrative law judge may not disregard, set aside, or otherwise review a national coverage decision (42 CFR §405.860) issued under §1862(a)(1) of the Act.

NOTE: Review any ECP local medical review policy that may be in place and perform provider education.

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

Supplies - Drugs

Diagnostic Services

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:

- o have esophageal involvement with progressive systemic sclerosis; or
- o have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction; or
- o are poor surgical risks for a valvuloplasty procedure; or
- o 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 levels (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. l4-3 § 2455, and HCFA Pub. l0 § 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 or 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) FOR SEVERE ANGINA--COVERED

External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. Although these and similar devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, Medicare coverage is limited to its use in patients with stable angina pectoris, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Other uses of this device and similar devices remain non-covered. In addition, the non-coverage of hydraulic versions of these types of devices remains in force.

Coverage is provided for the use of ECP for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because: (1) their condition is inoperable, or at high risk of operative complications or post-operative failure; (2) their coronary anatomy is not readily amenable to such procedures; or (3) they have co-morbid states which create excessive risk.

A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week. The patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and deflate in synchronization with the patient’s cardiac cycle.

During diastole the three sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole, which produces a rapid drop in vascular impedance, a decrease in ventricular workload and an increase in cardiac output.

The augmented diastolic pressure and retrograde aortic flow appear to improve myocardial perfusion, while systolic unloading appears to reduce cardiac workload and oxygen requirements. The increased venous return coupled with enhanced systolic flow appears to increase cardiac output. As a result of this treatment, most patients experience increased time until onset of ischemia, increased exercise tolerance, and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to two years.

This procedure must be done under direct supervision of a physician.

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 or 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.