Medicare Coverage Issues Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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CHANGE REQUEST 1884

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
35-71 – 35-72	2 pp.	2 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE:* November 15, 2001
IMPLEMENTATION DATE: November 15, 2001

Section 35-74, External Counterpulsation (ECP) for Severe Angina, is amended to indicate that this policy only pertains to ECP devices intended for the treatment of cardiac conditions. Other non-cardiac conditions in which end diastolic pneumatic compression devices may be considered for coverage are not considered under this policy

This revision to the Coverage Issues Manual (CIM) is a national coverage decision (NCD) made under ' 1862 (a)(1) of the Social Security Act (the Act). NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, and other contractors. Under 42 CFR 422.256 (b) an NCD that expands coverage is also binding on a Medicare+Choice organization. In addition, an administrative law judge may not review an NCD. (See ' 1869 (f)(1)(A)(i) of the Act.)

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 previous published in the manual and is only being reprinted.

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 ECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. 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.