
Medicare Coverage Issues Manual

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| <u>HEADER SECTION NUMBERS</u> | <u>PAGES TO INSERT</u> | <u>PAGES TO DELETE</u> |
|-------------------------------|------------------------|------------------------|
| 35-81 – 35-87 | 6 pp. | 4 pp. |

NEW/REVISED MATERIAL-- *EFFECTIVE DATE: October 1, 2003*
IMPLEMENTATION DATE: October 1, 2003

Section 35-85, Implantable Automatic Defibrillators, is revised to specify that we have expanded the coverage policy for: Coronary artery disease with a documented prior myocardial infarction (MI), a measured left ventricular ejection fraction ≤ 0.35 , and inducible, sustained ventricular tachyarrhythmia or ventricular fibrillation at electrophysiology study; or documented prior MI and a measured left ventricular ejection fraction ≤ 0.30 and a QRS duration of > 120 milliseconds.

Also in CIM §§ 35-85, we specify that: all other indications for defibrillators not otherwise specified in this section of the CIM remain noncovered except when furnished in accordance with Food and Drug Administration-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials as stated in 60 FR 48417.

This section of the CIM is the National Coverage Determination (NCD). The NCDs are binding on all carriers, intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), and NCD that expands Medicare 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 Social Security Act.)

Provider Education: You shall inform affected provider communities by posting relevant portions of this instruction on their websites within 2 weeks of receiving this instruction. In addition, the same information shall be published in your next regularly scheduled bulletin. If you have a listserv that targets the affected provider communities, you shall use it to notify your subscribers that information about a revised coverage determination for implantable automatic defibrillators is available on your Web site.

These instructions shall 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 CIM and is only being reprinted.

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 lithotripter. The lithotripter 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, transcystoscopic 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

Pancreas transplantation is performed to induce an insulin independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

Medicare has had a policy of not covering pancreas transplantation for many years as the safety and effectiveness of the procedure had not been demonstrated. The Office of Health Technology Assessment performed an assessment on pancreas-kidney transplantation in 1994. They found reasonable graft survival outcomes for patients receiving either simultaneous pancreas-kidney transplantation and pancreas after kidney transplantation.

Effective July 1, 1999, Medicare will cover whole organ pancreas transplantation (ICD-9-CM code 52.80, or 52.82, CPT code 48554) only when it is performed simultaneous with or after a kidney transplant (ICD-9-CM code 55.69, CPT code 50360, or 50365). If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy will begin with the date of discharge from the inpatient stay for the pancreas transplant.

Pancreas transplantation for diabetic patients who have not experienced end stage renal failure secondary to diabetes continues to be excluded from Medicare coverage. Medicare also excludes coverage of transplantation of partial pancreatic tissue or islet cells. There is not sufficient evidence at this time to support a determination that these procedures are reasonable and necessary.

35-83 24-HOUR AMBULATORY ESOPHAGEAL pH MONITORING--(Effective for services performed on or after June 11, 1985.)

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 psychosurgical 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 radio frequency 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 IMPLANTABLE AUTOMATIC DEFIBRILLATORS

The implantable automatic defibrillator (**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.

A. Covered Indications

1) Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause (effective July 1, 1991);

2) Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause (effective July 1, 1999);

3) Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy (effective July 1, 1999);

Additional indications effective for services performed on or after **October** 1, 2003:

4) Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction ≤ 0.35 , and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 4 weeks prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.);

5) Documented prior MI and a measured left ventricular ejection fraction ≤ 0.30 and a QRS duration of > 120 milliseconds. Patients must not have:

- a. New York Heart Association classification IV;
- b. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- c. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months;
- d. Had an enzyme-positive MI within past month;
- e. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
- f. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.

B. All patients considered for implantation of a defibrillator must not have irreversible brain damage, disease or dysfunction that precludes the ability to give informed consent.

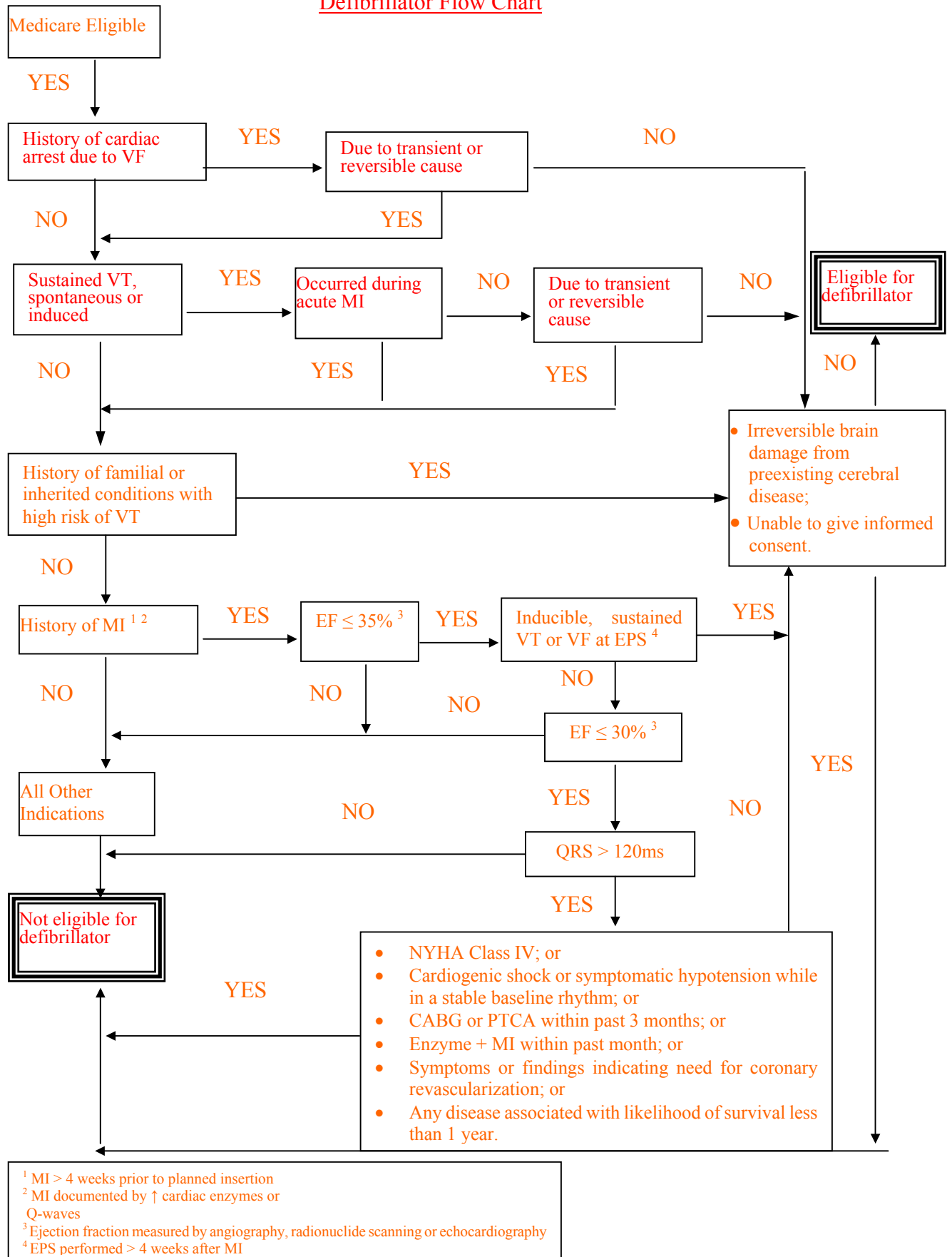
C. MIs must be documented by elevated cardiac enzymes or Q-waves on an electrocardiogram. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.

D. All other indications remain noncovered except in Category B IDE clinical trials (60 CFR 48417) or as a routine cost in clinical trials defined under CIM 30-1.

(See defibrillator flow chart next page.)

(This NCD last reviewed August 2003.)

Defibrillator Flow Chart



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 applications from consortia will not be approved.

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

- o 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

- o 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

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

- o 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:

- o 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;

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

- o 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 hospital 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 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"). Medicare does cover a ventricular assist device (VAD) when used in conjunction with specific criteria listed in CIM §65-15.

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

Extracorporeal photopheresis 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.

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