
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

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

Transmittal 29

Date: MARCH 4, 2005

CHANGE REQUEST 3604

SUBJECT: Implantable Automatic Defibrillators

I. SUMMARY OF CHANGES: The Centers for Medicare & Medicaid Services (CMS) is expanding national coverage for implantable automatic defibrillators by including new indications.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 27, 2005
IMPLEMENTATION DATE: January 27, 2005
IMPLEMENTATION QR MODIFIER: April 4, 2005

(This revision to section 20.4, of Pub. 100-03, is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. The NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR §§405.732, 405.860). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an Administrative Law Judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

II. CHANGES IN MANUAL INSTRUCTIONS: (R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/20.4/Implantable Automatic Defibrillators (Various Effective Dates Below)

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
x	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations

Table of Contents (Rev. 29, 03-04-05)

20.4 – Implantable Automatic Defibrillators (Various Effective Dates Below)

20.4 - Implantable Automatic Defibrillators (Various Effective Dates Below)

(Rev. 29, Issued: 03-04-05, Effective: 01-27-05, Implementation: 01-27-05, Implementation QR Modifier: 04-04-05)

A. General

The implantable automatic 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.

B. 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 (LVEF) ≤ 0.35 , and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days 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 LVEF ≤ 0.30 and a QRS duration of >120 milliseconds (*the QRS restriction does not apply to services performed on or after January 27, 2005*). Patients must not have:
 - a. New York Heart Association (NYHC) 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 (*Effective for services on or after January 27, 2005, patients must not have an acute MI in the past 40 days*);
- 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.

Additional indications effective for services performed on or after January 27, 2005:

- 6. *Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF \leq 35%;*
- 7. *Patients with non-ischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF \leq 35%;*
- 8. *Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;*

All indications must meet the following criteria:

- a. *Patients must not have irreversible brain damage from preexisting cerebral disease;*
- b. *MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;¹*

¹ Alpert and Thygesen et al., 2000.

Criteria for acute, evolving or recent MI.

Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI:

- 1) *Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:*
 - a) *ischemic symptoms;*
 - b) *development of pathologic Q waves on the ECG;*
 - c) *ECG changes indicative of ischemia (ST segment elevation or depression); or*
 - d) *coronary artery intervention (e.g., coronary angioplasty).*
- 2) *Pathologic findings of an acute MI.*

Criteria for established MI.

Any one of the following criteria satisfies the diagnosis for established MI:

Indications 3 - 8 (primary prevention of sudden cardiac death) must also meet the following criteria:

- a. Patients must be able to give informed consent;*
- b. Patients must not have:*
 - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;*
 - Had a CABG or PTCA within the past 3 months;*
 - Had an acute MI within the past 40 days;*
 - Clinical symptoms or findings that would make them a candidate for coronary revascularization;*
 - Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;*
- c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;*
- d. The beneficiary receiving the defibrillator implantation for primary prevention is enrolled in either a Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (National Coverage Determination (NCD) Manual §310.1) or a qualifying data collection system including approved clinical trials and registries. Initially, an implantable cardiac defibrillator (ICD) database will be maintained using a data submission mechanism that is already in use by Medicare participating hospitals to submit data to the Iowa Foundation for Medical Care (IFMC)--a Quality Improvement Organization (QIO) contractor--for determination of reasonable and necessary and quality improvement. Initial hypothesis and data elements are specified in this decision (Appendix VI) and are the minimum necessary to ensure that the device is reasonable and necessary. Data collection will be completed using the ICDA (ICD Abstraction Tool) and transmitted via QNet (Quality Network Exchange) to the IFMC who will collect and maintain the database. Additional stakeholder-developed data collection systems to augment or replace the initial QNet system, addressing at a minimum the hypotheses specified in this decision, must meet the following basic criteria:*

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- 1) Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed.*
 - 2) Pathologic findings of a healed or healing MI.*

- *Written protocol on file;*
- *Institutional review board review and approval;*
- *Scientific review and approval by two or more qualified individuals who are not part of the research team;*
- *Certification that investigators have not been disqualified.*

For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

- f. *Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the patient's medical record.*
9. *Patients with NIDCM >3 months, NYHA Class II or III heart failure, and measured LVEF \leq 35%, only if the following additional criteria are also met:*
 - a. *Patients must be able to give informed consent;*
 - b. *Patients must not have:*
 - *Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;*
 - *Had a CABG or PTCA within the past 3 months;*
 - *Had an acute MI within the past 40 days;*
 - *Clinical symptoms or findings that would make them a candidate for coronary revascularization;*
 - *Irreversible brain damage from preexisting cerebral disease;*
 - *Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;*
 - c. *Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;*
 - d. *MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;²*
 - e. *The beneficiary receiving the defibrillator implantation for this indication is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1), or a prospective data collection system meeting the following basic criteria:*
 - *Written protocol on file;*

² *Ibid.*

- *Institutional Review Board review and approval;*
- *Scientific review and approval by two or more qualified individuals who are not part of the research team;*
- *Certification that investigators have not been disqualified.*

For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

- f. *Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the patient's medical record.*

C. Other Indications

All other indications for implantable automatic defibrillators not currently covered in accordance with this decision will continue to be covered under Category B IDE trials (42 CFR §405.201) and the CMS routine clinical trials policy (NCD §310.1).

(This NCD last reviewed February 2005.)