

# Coverage Guidelines for CRM and EP Devices

**GuidePoint**

Simplifying Reimbursement

**Cardiac Rhythm Management  
and Electrophysiology**

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## Indications and Coverage Determinations

This document outlines the general coverage policies for CRM devices. CMS establishes national Medicare coverage policy, but its contractor payers may provide local guidance with more detailed—yet sometimes differing—billing and coding instructions.

### National Coverage Determinations

The Centers for Medicare & Medicaid Services (CMS) publishes national coverage determinations (NCDs) to specify the extent to which Medicare will cover specific services, procedures, or technologies on a national basis. Local Medicare contractor payers are required to follow these NCDs where they exist. Where they do not exist, it is up to the Medicare contractor to make local coverage determinations (LCDs). Roughly 90 percent of all health care services are covered at the local contractor level, and 10 percent at the national level through the publication of an NCD. Medicare has applicable NCDs for AICDs, cardiac pacemakers, and cardiac pacemaker follow-up services. They can be found at <http://www.cms.hhs.gov/CoverageGenInfo/>.

### Medicare NCD for Cardiac Pacemakers<sup>1</sup>

#### *Item/Service Description*

Cardiac pacemakers are self-contained, battery-operated units that send electrical stimulation to the heart. They are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate and/or rhythm. Pacemakers are generally used for persistent, symptomatic second- or third-degree atrioventricular (AV) block, and symptomatic sinus bradycardia.

#### *Indications and Limitations of Coverage*

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the following conditions and limitations. While cardiac pacemakers have been covered under Medicare for many years, there were no specific guidelines for their use other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for cardiac pacing on or after the effective dates of this instruction are subject to these guidelines, which are based on certain assumptions regarding the clinical goals of cardiac pacing. While some uses of pacemakers are relatively certain or unambiguous, many other uses require considerable expertise and judgment.

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<sup>1</sup> Centers for Medicare and Medicaid Services. National Coverage Determination for Cardiac Pacemakers (20.8). In: Medicare Coverage Database. Effective April 30, 2004. Available at: [http://www.cms.hhs.gov/mcd/viewncd.asp?ncd\\_id=20.8&ncd\\_version=2&basket=ncd%3A20%2E8%3A2%3ACardiac+Pacemakers](http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.8&ncd_version=2&basket=ncd%3A20%2E8%3A2%3ACardiac+Pacemakers). Accessed September 1, 2009.

Consequently, the medical necessity for permanent cardiac pacing must be viewed in the context of overall patient management. The appropriateness of such pacing may be conditional on other diagnostic or therapeutic modalities having been undertaken.

Although significant complications and adverse side effects of pacemaker use are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which permanent cardiac pacing may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected.

Consequently, judgments about the medical necessity and acceptability of new uses for cardiac pacing in new classes of patients may change as more conclusive evidence becomes available. This instruction applies only to permanent cardiac pacemakers, and does not address the use of temporary, non-implanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacing for patients in general. These are intended as guidelines in assessing the medical necessity for pacing therapies, taking into account the particular circumstances in each case. However, as a general rule, the two groups of current medical concepts may be viewed as representing:

- Group I: Single-chamber Cardiac Pacemakers—a) conditions under which single-chamber pacemaker claims may be considered covered without further claims development; and b) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances sufficient to convince the contractor that the claim should be paid.
- Group II: Dual-chamber Cardiac Pacemakers—a) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and b) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single- and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

CMS opened the NCD on Cardiac Pacemakers to afford the public an opportunity to comment on the proposal to revise the language contained in the instruction. The revisions transfer the focus of the NCD from the actual pacemaker implantation procedure itself to the reasonable and necessary medical indications that justify cardiac pacing. This is consistent with our findings that pacemaker implantation is no longer considered routinely harmful or an experimental procedure.

### ***Group I. Single-chamber Cardiac Pacemakers***

*Effective March 16, 1983*

#### **A. Nationally Covered Indications**

Conditions under which cardiac pacing is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity).

1. Acquired complete (also referred to as third-degree) AV heart block.
2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.
3. Second-degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat. P-R interval indicates the time taken for an impulse to travel from the atria to the ventricles on an electrocardiogram).

4. Second-degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.
5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
7. Sinus bradycardia is the consequence of long-term necessary drug treatment for which there is no acceptable alternative when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness, or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block (i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest) when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness, or confusion).
9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).
10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high-degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness, or confusion).
11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.
12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.
13. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third-degree) and/or Mobitz Type II second-degree AV block in association with bundle branch block.
14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

*Effective May 9, 1985*

15. Second-degree AV heart block of Type I with the QRS complexes prolonged.

#### B. Nationally Noncovered Indications

Conditions which, although used by some physicians as a basis for permanent cardiac pacing, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of the above indications. Contractors should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim, since additional claims development may be required. The object of such further development is to establish whether the particular claim actually meets the conditions in A above. In claims where this is not the case or where such an event appears unlikely, the contractor may deny the claim.

1. Syncope of undetermined cause.
2. Sinus bradycardia without significant symptoms.
3. Sino-atrial block or sinus arrest without significant symptoms.
4. Prolonged P-R intervals with atrial fibrillation (without third-degree AV block) or with other causes of transient ventricular pause.
5. Bradycardia during sleep.

6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.
7. Asymptomatic second-degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His bundle (a component of the electrical conduction system of the heart).

*Effective October 1, 2001*

8. Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy.

## **Group II. Dual-chamber Cardiac Pacemakers**

*Effective May 9, 1985*

### A. Nationally Covered Indications

Conditions under dual-chamber cardiac pacing are considered acceptable or necessary in the general medical community unless conditions 1 and 2 under Group II. B. are present:

1. Patients in whom single-chamber pacing (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.
2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.
3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with congestive heart failure despite adequate other medical measures.
4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people.
5. Dual-chamber pacemakers may also be covered for the conditions as listed in Group I. A., if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

### B. Nationally Noncovered Indications

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium).
2. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia.
3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, (e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures).
4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third-degree) and/or Type II second-degree AV block in association with bundle branch block.

### C. Other

All other indications for dual-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally noncovered, except for Category B IDE clinical trials, or as routine costs of dual-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual. (This NCD last reviewed June 2004).

## Pacemaker—Evaluation Services<sup>2</sup>

### *Item/Service Description*

There are two general types of pacemakers in current use—single-chamber pacemakers, which sense and pace the ventricles of the heart, and dual-chamber pacemakers, which sense and pace both the atria and the ventricles. These differences require different monitoring patterns over the expected life of the units involved.

### **Indications and Limitations of Coverage**

Medicare covers a variety of services for the post-implant follow-up and evaluation of implanted cardiac pacemakers. The following guidelines are designed to assist contractors in identifying and processing claims for such services.

Note: These new guidelines are limited to lithium battery-powered pacemakers, because mercury-zinc battery-powered pacemakers are no longer being manufactured and virtually all have been replaced by lithium units. Contractors still receiving claims for monitoring such units should continue to apply the guidelines published in 1980 to those units until they are replaced.

One fact of which contractors should be aware is that many dual-chamber units may be programmed to pace only the ventricles; this may be done either at the time the pacemaker is implanted or at some time afterward. In such cases, a dual-chamber unit, when programmed or reprogrammed for ventricular pacing, should be treated as a single-chamber pacemaker in applying screening guidelines.

The decision as to how often any patient's pacemaker should be monitored is the responsibility of the patient's physician, who is best able to take into account the condition and circumstances of the individual patient. These may vary over time, requiring modifications of the frequency with which the patient should be monitored. In cases where monitoring is done by some entity other than the patient's physician, such as a commercial monitoring service or hospital outpatient department, the physician's prescription for monitoring is required and should be periodically renewed (at least annually) to assure that the frequency of monitoring is proper for the patient.

*Where a patient is monitored both during clinic visits and transtelephonically<sup>3</sup>, the contractor should be sure to include frequency data on both types of monitoring in evaluating the reasonableness of the frequency of monitoring services received by the patient.*

Since there are more than 200 pacemaker models in service at any given point, and a variety of patient conditions that give rise to the need for pacemakers, the question of the appropriate frequency of monitorings is a complex one. Nevertheless, it is possible to develop guidelines within which the vast majority of pacemaker monitorings will fall, and contractors should do this, using their own data and experience, as well as the frequency guidelines that follow, in order to limit extensive claims development to those cases requiring special attention.

<sup>2</sup> Centers for Medicare and Medicaid Services. National Coverage Determination for Cardiac Pacemaker Evaluation Services (20.8.1). In: Medicare Coverage Database. Effective October 1, 1984. Available at: [http://www.cms.hhs.gov/mcd/viewncd.asp?ncd\\_id=20.8.1&ncd\\_version=1&basket=ncd%3A20%2E8%2E1%3A1%3ACardiac+Pacemaker+Evaluation+Services](http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.8.1&ncd_version=1&basket=ncd%3A20%2E8%2E1%3A1%3ACardiac+Pacemaker+Evaluation+Services). Accessed September 1, 2009.

<sup>3</sup> Centers for Medicare and Medicaid Services. Coverage determinations: Transtelephonic monitoring of cardiac pacemakers. In: Medicare National Coverage Determinations Manual. CMS Pub. 100-3; Chapter 1, Part 1, Section 20.8.1.1. October 3, 2003. Available at: [http://www.cms.hhs.gov/manuals/downloads/ncd103c1\\_Part1.pdf](http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part1.pdf). Accessed September 1, 2009.  
See page 12 for important information about the uses and limitations of this document. CRM5-1727-0310

## **Pacemaker Clinic Services**

### 1. General

Pacemaker monitoring is also covered when done by pacemaker clinics. Clinic visits may be done in conjunction with transtelephonic monitoring or as a separate service; however, the services rendered by a pacemaker clinic are more extensive than those currently possible by telephone. They include, for example, physical examination of patients and reprogramming of pacemakers. Thus, the use of one of these types of monitoring does not preclude concurrent use of the other.

### 2. Frequency Guidelines

The frequency of clinic visits is the decision of the patient's physician, taking into account, among other things, the medical condition of the patient. However, contractors can develop monitoring guidelines that will prove useful in screening claims. The following are recommendations for monitoring guidelines on lithium-battery pacemakers:

#### *Medicare's Frequency Guidelines for Pacemaker Clinic Services*

- For single-chamber pacemakers—twice in the first 6 months following implant, then once every 12 months
- For dual-chamber pacemakers—twice in the first 6 months, then once every 6 months

### **Pacemaker—Temporary**

At this time there is no specific Medicare National Coverage Determination (NCD) for temporary pacemakers. It is important for medical providers to check with their local Medicare contractor or non-Medicare payers to determine patient coverage and coding/billing guidelines.

Note: Search the Medicare Coverage Database on the CMS website (<http://www.cms.hhs.gov/mcd/search.asp>) for coverage descriptions and updates.

## **Medicare NCD for Implantable Cardioverter Defibrillators (ICDs)<sup>4</sup>**

*Effective date of this version: January 27, 2005*

*Implementation date: January 27, 2005*

### **Item/Service Description**

#### 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. Indications and Limitations of Coverage

#### 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:

<sup>4</sup> Centers for Medicare and Medicaid Services. National Coverage Determination for Implantable Automatic Defibrillators (20.4). In: Medicare Coverage Database. March 4, 2005. Available at: <http://www.cms.hhs.gov/transmittals/downloads/R29NCD.pdf>. Accessed September 1, 2009.

4. Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF)  $\leq 0.35$ , 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  $\leq 0.30$  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 had 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 and 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\*

Indications 3–8 (primary prevention of sudden cardiac death) must also meet the following criteria<sup>5</sup>:

- 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

<sup>5</sup> Heart Rhythm Society. Expanded ICD Coverage for Primary Prevention, February 23, 2005. Available at: <http://www.hrsonline.org/Policy/ICDRegistry/>. Accessed September 1, 2009.

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 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:

- 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.

- e. 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;\*

\*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:

- 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.

- 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;
  - 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 Manual §310.1).

(This NCD last reviewed February 2005.)

### **Medicare NCD for Cardiac Resynchronization Therapy Pacemakers (CRT-Ps)**

A cardiac resynchronization therapy pacemaker (CRT-P) utilizes biventricular pacing to coordinate the contraction of the ventricles with the intent of improving the hemodynamic status of the patient. This technology utilizes both conventional pacing technology as well as the addition of a third electrode that provides sensing and pacing capabilities in the left ventricle.

At this time there is no specific NCD for CRT-Ps. However, some Medicare contractors have developed LCDs for CRT-P that apply to certain regions. It is important for medical providers to check with their local Medicare contractor or non-Medicare payers to determine patient coverage and coding/billing guidelines.

### **Medicare NCD for Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)**

A cardiac resynchronization therapy defibrillator (CRT-D) utilizes biventricular pacing to coordinate the contraction of the ventricles and ICD capabilities to prevent ventricular tachyarrhythmias and ultimately the prevention of sudden cardiac death.

At this time there is no specific NCD for CRT-Ds. However, some Medicare contractors have developed LCDs for CRT-D that apply to certain regions. It is important for medical providers to check with their local Medicare contractor or non-Medicare payers to determine patient coverage and coding/billing guidelines.

## Medicare NCD for Intracardiac Electrophysiology and Related Procedures

Some cardiovascular procedures, such as pacemakers and cardioverter defibrillators, contain very clear national coverage criteria as defined by CMS. Other procedures, such as electrophysiology studies (EPS), do not have clearly defined coverage criteria at the national level. Some Medicare contractors have developed LCDs for EPS that apply to certain regions. It is important for providers to check with their local Medicare contractor or non-Medicare payers to determine patient coverage and coding/billing guidelines.

Note: Search the Medicare Coverage Database on the CMS website (<http://www.cms.hhs.gov/mcd/search.asp>) for coverage descriptions and updates.

## ICD National Coverage

In the requirements for new ICD coverage, Medicare distinguishes between primary prevention of sudden cardiac death, meaning patients with no history of induced or spontaneous arrhythmia, and secondary prevention, meaning patients with a documented cardiac arrest or sustained ventricular tachyarrhythmia. For patients meeting the primary prevention indications, the providers (hospitals and physicians) must be able to justify the medical necessity of devices other than single-lead devices. This medical necessity must be documented in the patient's medical record.

## National Coverage for Device Follow-up

There is an NCD for cardiac pacemaker evaluation services (post implant). There is no NCD, however, for ICD or CRT evaluation services (post implant). In the absence of national coverage guidelines, providers should consult their local Medicare contractor's guidance.

Code descriptors for the new 2009 CPT codes relating to cardiac device monitoring indicate minimum frequencies for in-person and remote monitoring<sup>6</sup>. As Medicare establishes local coverage policies around these codes, frequency will become a focal point for coverage. The Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA) have published the HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIED): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations. This document makes recommendations for follow-up based on the type of cardiac device and may be helpful as a guide to reimbursement billing practices. It is available online at [http://www.hrsonline.org/Policy/ClinicalGuidelines/upload/cieds\\_guidelines.pdf](http://www.hrsonline.org/Policy/ClinicalGuidelines/upload/cieds_guidelines.pdf)

<sup>6</sup> American Medical Association. Current Procedural Terminology (CPT®) 2009 Professional Edition. Chicago, IL: 2008.

The table below summarizes the CMS coverage decisions for follow-up pacemaker device evaluation services. It provides the key wording from the NCD for pacemaker evaluation services. As you can see, the decision regarding the required frequency for pacemaker follow-up is a very complex issue, and Medicare allows the physician to make a medical necessity judgment call based on the type of device.

### **Medicare Guidelines for Pacemaker Follow-Up Frequency**

Types of pacemakers	There are two general types of pacemakers in current use: single-chamber pacemakers, which sense and pace the ventricles of the heart, and dual-chamber pacemakers, which sense and pace both the atria and the ventricles. These differences require different monitoring patterns over the expected life of the units involved.
Deciding frequency	The decision as to how often any patient's pacemaker should be monitored is the responsibility of the patient's physician, who is best able to take into account the condition and circumstances of the individual patient. These may vary over time, requiring modifications of the frequency with which the patient should be monitored. In cases where monitoring is done by some entity other than the patient's physician, such as a commercial monitoring service or hospital outpatient department, the physician's prescription for monitoring is required and should be periodically renewed (at least annually) to ensure that the frequency of monitoring is proper for the patient.
Developing local guidelines	Since there are over 200 pacemaker models in service at any given point, and a variety of patient conditions that give rise to the need for pacemakers, the question of the appropriate frequency of monitoring is a complex one. Nevertheless, it is possible to develop guidelines within which the vast majority of pacemaker monitoring will fall. Contractors should do this, using their own data and experience, as well as the frequency guidelines which follow, in order to limit extensive claims development to those cases requiring special attention.

As a result, each local contractor may have a frequency guideline for follow-up pacemaker services. Providers should check their local contractor's website for more details. To ensure appropriate payment, there are two good general rules:

- Always verify that the physician documentation establishes medical necessity for the frequency of device analysis.
- Also, local coverage policies may identify specific diagnosis codes that are required for establishing medical necessity for coverage and payment. These should also be documented by the physician.

Medicare currently does not have an NCD for remote monitoring of CRM technology other than transtelephonic pacemaker analysis. Most of these procedures and devices are covered at the local Medicare contractor level.

## **Local Coverage Determinations**

A local coverage determination is a decision by a Medicare contractor payer about whether to cover a particular service based on whether the service is reasonable and necessary.

LCDs play an important role in ensuring appropriate payment for CRM services. They often give precise instructions on the diagnosis and procedure codes that must be reported in order to receive payment, as well as other billing guidance. You should become familiar with the requirements specified in the coverage decisions issued by the payer for your state or Medicare region.

## **Cardiac Resynchronization Therapy Pacemakers (CRT-Ps)**

At this time there is no specific NCD for CRT-Ps. However, some Medicare contractors have developed LCDs for CRT-P that apply to certain regions. It is important for medical providers to check with their local Medicare contractor or non-Medicare payers to determine patient coverage and coding/billing guidelines.

## Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)

At this time there is no specific NCD for CRT-Ds. However, some Medicare contractors have developed LCDs for CRT-D that apply to certain regions. It is important for medical providers to check with their local Medicare contractor or non-Medicare payers to determine patient coverage and coding/billing guidelines.

## Intracardiac Electrophysiology and Related Procedures

Some cardiovascular procedures, such as pacemakers and cardioverter defibrillators, contain very clear national coverage criteria as defined by CMS. Other procedures, such as electrophysiology studies (EPS), do not have clearly defined coverage criteria at the national level. Some Medicare contractors have developed LCDs for EPS that apply to certain regions. It is important for providers to check with their local Medicare contractor or non-Medicare payers to determine patient coverage and coding/billing guidelines.

Note: Search the Medicare Coverage Database on the CMS website (<http://www.cms.hhs.gov/mcd/search.asp>) for coverage descriptions and updates.

## Disclaimer

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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.



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### Cardiac Rhythm Management

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