Internal Cardiac Defibrillators and Pacemakers for Prevention of Sudden Death

Policy Number: HS-199

Original Effective Date: 4/11/2013

Revised Date(s): 3/6/2014; 3/5/2015

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline

INTERNAL CARDIAC DEFIBRILLATORS AND PACEMAKERS FOR PREVENTION OF SUDDEN DEATH

HS-199

DISCLAIMER
The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. Note: The lines of business (LOB) are subject to change without notice; consult www.wellcare.com/Providers/CCGs for list of current LOBs.

BACKGROUND
Heart failure is common and rapidly increasing in incidence. It carries a poor prognosis, with an estimated 1-year mortality of 30–50% for patients with advanced disease. It is also associated with a high burden of illness, high resource utilization, and frequent hospitalizations. The current treatment for heart failure involves addressing the underlying cause(s), lifestyle modifications, and pharmacologic interventions. In the majority of cases, treatment is not curative but intended to ameliorate symptoms and improve function. Approximately 20–30% of patients with heart failure exhibit dysynchronous contractions of the left and right ventricles due to conduction system disease. Dyssynchrony further depresses the already impaired pumping ability of the heart. The New York Heart Association (NYHA) classes for heart failure are defined as follows (CMS, 2012):

Class I: Individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.

Class II: Individuals with cardiac disease resulting in a slight limitation of physical activity; they are comfortable at rest; ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.

Class III: Individuals with cardiac disease resulting in a marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

Class IV: Individuals with cardiac disease resulting in the inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Automatic Implantable Cardiac Defibrillators (AICDs) (CMS, 2012)
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.

Biventricular Pacing (CMS, 2012)
Biventricular pacing (or Cardiac Resynchronization Therapy [CRT] or Cardiac Resynchronization Therapy Pacemaker [CRT-P]) refers to reestablishing synchronous contraction between the left ventricular free wall and the ventricular septum in an attempt to improve left ventricular efficiency and, subsequently, to improve functional class. Generally, CRT has been used to describe biventricular pacing, but cardiac resynchronization can be achieved by left ventricular pacing only in some patients. Selected patients with moderate to severe heart failure may benefit from CRT or biventricular pacing. CRT, in combination with stable optimal medical therapy, may help the lower chambers of the heart beat together and improve the heart’s ability to supply blood and oxygen to the body. CRT is designed to help the right (RV) and left ventricle (LV) beat at the same time in a normal sequence treating ventricular dyssynchrony.
An implantable biventricular pacemaker is an advanced version of a standardized implantable pacemaker. The biventricular pacemaker is implanted in the muscle tissue of the chest, below the collarbone, or in the abdomen. Three leads or wires, one atrial lead [right atrium] and two ventricular leads [right and left ventricles], are transvenously connected from the pacemaker to both sides of the heart. Once the pacemaker is implanted, it is programmed so that both ventricles are stimulated to contract after atrial contraction with the goal of improving left ventricle function, reducing presystolic mitral regurgitation, and improving LV diastolic filling time. The most frequently reported complication of CRT is lead dislodgement, which occurs in approximately 9% of patients.

**Pacemakers (CMS, 2004; CMS, 1984)**

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. 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). 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 two groups of conditions outlined below deal with the necessity for cardiac pacing for patients in general:

- **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 exist of the sufficiency 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.

**POSITION STATEMENT**

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**Automatic Implantable Cardiac Defibrillators (AICDs)**

Automatic implantable cardiac defibrillators (AICDs) are a covered benefit for the indications below (InterQual, 2013):

1. Cardiac arrest survivor with or without concomitant acute myocardial infarction (MI); OR,
2. Sustained V tach (>30 secs); OR,
3. Nonsustained V tach (<= 30 secs); OR,
4. Inducible V fib at EP testing; OR,
5. Ischemic cardiomyopathy by testing; OR,
6. Nonischemic dilated cardiomyopathy; OR,
7. Hypertrophic cardiomyopathy by testing; OR,
8. Brugada syndrome; OR,
For placement of AICDs, additional criteria is noted for the three conditions below (CMS, 2012):

**Ventricular Fibrillation/Flutter Absent Myocardial Infarction (MI)**

1. Documented episode of cardiac arrest due to Ventricular Fibrillation (VF), not due to a transient or reversible cause.
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.
3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy.

**Myocardial Infarction (MI)**

1. 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 four weeks after the qualifying MI.)
2. Documented prior MI, and a measured LVEF ≤0.30.

Any 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:
   - Ischemic symptoms.
   - Development of pathologic Q waves on the ECG.
   - ECG changes indicative of ischemia (ST segment elevation or depression).
   - Coronary artery intervention (e.g., coronary angioplasty).

   OR,

2. Pathologic findings of an acute MI as evidenced by any one of the following:
   - 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.
   - Pathologic findings of a healed or healing MI.

**Dilated Cardiomyopathy**

1. Patients with Ischemic Dilated Cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure and measured LVEF ≤35 percent.
2. Patients with Non-Ischemic Dilated Cardiomyopathy (NIDCM) > three months, NYHA Class II and III heart failure and measured LVEF ≤35 percent.
3. Patients who meet all current CMS coverage requirements for a Cardiac Resynchronization Therapy (CRT) device and have NYHA Class IV heart failure.

NOTE: *ICD-9 428.43: Medical record must document patient meets the NYHA Class IV heart failure criteria and/or is unable to carry out any physical activity without discomfort, has symptoms of cardiac insufficiency at rest and if any physical activity is undertaken, discomfort is increased.

All indications must also meet the following criteria - patients must not have:
- Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; OR,
- Had a CABG or PTCA within the past 3 months; OR,
- Had an acute MI within the past 40 days; OR,
• Clinical symptoms or findings that would make them a candidate for coronary revascularization; OR,
• Irreversible brain damage from preexisting cerebral disease; OR,
• Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year; OR,
• Ejection fractions must be measured by angiography, radionuclide scanning or echocardiography; OR,
• 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 (see criteria above).

In addition, the following criteria must be met (CMS, 2005):

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

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; OR,

3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy; OR,

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.); OR,

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

6. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF < 35%; OR,

7. Patients with non-ischemic dilated cardiomyopathy (NIDCM) >9 months, NYHA Class II and III heart failure, and measured LVEF < 35%; OR,

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.

9. Patients with NIDCM >3 months, NYHA Class II or III heart failure, and measured LVEF < 35%, only if the following additional criteria are also met:
   a. Patients must be able to give informed consent; AND,
   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;

AND,

c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; AND,

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; AND,

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.

AND,

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.

In addition to the criteria above, for Indications 1-8 above, ALL indications must meet the following criteria:

a. Patients must not have irreversible brain damage from preexisting cerebral disease; AND,

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.

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

a. Patients must be able to give informed consent; AND,

b. Patients must not have:
   • Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; OR,
   • Had a CABG or PTCA within the past 3 months; OR,
   • Had an acute MI within the past 40 days; OR,
   • Clinical symptoms or findings that would make them a candidate for coronary revascularization; OR,
   • Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.

AND,

c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; AND,

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:

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

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.

**Biventricular Pacing**

Biventricular pacing (also known as cardiac resynchronization therapy) is considered medically necessary when either of the following criteria are met:

1. New York Heart Association (NYHA) classification of heart failure III or IV AND all of the following:
   - Sinus rhythm, or chronic atrial fibrillation (AF), or frequent dependence on ventricular pacing; AND,
   - Left ventricular ejection fraction (LVEF) less than or equal to 35%; AND,
   - QRS duration greater than or equal to 120 msec; AND,
   - Member is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated: angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, beta blocker, digoxin, or diuretics; AND,
   - The device is approved by the Food and Drug Administration (FDA) for this indication.

OR,

2. NYHA classification of heart failure II AND all of the following:
   - Sinus rhythm; AND,
   - No evidence of atrial arrhythmia; AND,
   - Left ventricular ejection fraction (LVEF) less than or equal to 30%; AND,
   - Left bundle branch block with QRS duration greater than or equal to 130 msec; AND,
   - Member is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated: angiotensin-converting enzyme inhibitor, angiotensin receptor blocker; beta blocker; digoxin, or diuretics; AND,
   - The device is FDA approved for this indication.

Medicare will consider cardiac resynchronization therapy with implantable cardioverter defibrillator (ICD) system (CRT-D) medically necessary for patients at high risk for life-threatening ventricular arrhythmia or sudden cardiac arrest when the following criteria are met:
The aforementioned criteria for CRT-P are met (1 or 2); AND,
Member meets a covered indication in CMS’s National Coverage Determination Manual for Implantable automatic defibrillators (NCD 20.4) as outlined above under section AICDs AND,
The device is FDA approved for the indication.

Pacemakers (CMS, 2004)

Group I: Single-Chamber Cardiac Pacemakers

The following 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.

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

The following indications are not a covered benefit:

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).
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)

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 (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, etc.

NOTE: 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.

The following indications are not a covered benefit:

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.

Pacemaker Monitoring

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 trans-telephonically, 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. (CMS, 1984).

Self-contained pacemaker monitors are accepted devices for monitoring cardiac pacemakers (CMS, n.d.).

*Digital Electronic Pacemaker Monitors* provide patients with an instantaneous digital readout of the pacemaker pulse rate. Use of this device does not involve professional services until there has been a change of five pulses (or more) per minute above or below the initial rate of the pacemaker; when such change occurs, the patient contacts his physician.

*Audible/Visible Signal Pacemaker Monitor* produce an audible and visible signal which indicates the pacemaker rate. Use of this device does not involve professional services until a change occurs in these signals; at such time, the patient contacts his physician.

Note: The design of the self-contained pacemaker monitor makes it possible for the patient to monitor his pacemaker periodically and minimizes the need for regular visits to the outpatient department of the provider. Therefore, documentation of the medical necessity for pacemaker evaluation in the outpatient department of the provider should be obtained where such evaluation is employed in addition to the self-contained pacemaker monitor used by the patient in his home.

*Transtelephonic monitoring* of pacemakers is furnished by commercial suppliers, hospital outpatient departments and physician's offices. Telephone monitoring of cardiac pacemakers is medically efficacious in identifying early signs of possible pacemaker failure, thus reducing the number of sudden pacemaker failures requiring emergency replacement (CMS, 2003).

NOTE: The transmitting device furnished to the patient is simply one component of the diagnostic system, and is not covered as durable medical equipment. Those engaged in transtelephonic pacemaker monitoring should reflect the costs of the transmitters in setting their charges for monitoring.

**Monitoring via Specialize Clinics and Transtelephonically** (CMS, 2003)

In order for transtelephonic monitoring services to be covered, the services must consist of the following elements and adhere to one of the two sets of guidelines outlined below:

- A minimum 30-second readable strip of the pacemaker in the free-running mode; **AND,**
- Unless contraindicated, a minimum 30-second readable strip of the pacemaker in the magnetic mode; **AND,**
- A minimum 30 seconds of readable ECG strip.

**Guideline II Monitoring Guideline**

For single-chamber pacemakers:
- Every 2 weeks during Month 1.
- Every 12 weeks during Months 2 – 48.
- Every 8 weeks during Months 49 – 72.
- Every 4 weeks during Month 72 through failure.

For dual-chamber pacemakers:
- Every 2 weeks during Month 1.
- Every 12 weeks during Months 2 – 30.
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. The frequency of clinic visits is the decision of the patient’s physician, taking into account the member’s medical condition. The following are recommendations for monitoring guidelines on lithium-battery pacemakers:

- 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.

**Coding**

**Covered CPT® Codes**

- **33206** Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
- **33207** Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
- **33208** Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial & ventricular
- **33212** Insertion of pacemaker pulse generator only; with existing single lead
- **33213** Insertion of pacemaker pulse generator only; with existing dual leads
- **33214** Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new generator)
- **33215** Repositioning of previously implanted transvenous pacemaker or pacing cardioverter-defibrillator (right atrial or right ventricular) electrode
- **33216** Insertion of a single transvenous electrode, permanent pacemaker or cardioverter-defibrillator
- **33217** Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator
- **33218** Repair of single transvenous electrode, permanent pacemaker or pacing cardioverter-defibrillator
- **33220** Repair of 2 transvenous electrodes for permanent pacemaker or pacing cardioverter-defibrillator
- **33221** Insertion of pacemaker generator only; with existing multiple leads
- **33222** Revision or relocation of skin pocket for pacemaker
- **33223** Revision of skin pocket for cardioverter-defibrillator
- **33224** Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
- **33225** Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator(e.g., for upgrade to dual chamber system (List separately in addition to code from primary procedure)
- **33226** Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
- **33227** Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system
- **33228** Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system
- **33229** Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system
- **33230** Insertion of pacing cardioverter-defibrillator pulse generator only; with existing dual leads
- **33231** Insertion of pacing cardioverter-defibrillator pulse generator only; with existing multiple leads
- **33240** Insertion of pacing cardioverter-defibrillator pulse generator only; with existing single lead
- **33241** Removal of pacing cardioverter-defibrillator pulse generator only
- **33243** Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy
- **33244** Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by transvenous extraction
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33249 Insertion of replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s) single or dual chamber
33262 Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system
33263 Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system
33264 Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system

HCPCS® Codes
C1721 Cardioverter-defibrillator, dual chamber (implantable)
C1722 Cardioverter-defibrillator, single chamber (implantable)
C1777 Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1779 Lead, pacemaker, transvenous VDD single pass
C1785 Pacemaker, dual chamber, rate-responsive (implantable)
C1786 Pacemaker, single chamber, rate-responsive (implantable)
C1882 Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895 Lead, cardioverter-defibrillator, other than endocardial dual coil (implantable)
C1896 Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1898 Lead, pacemaker, other than VDD single pass
C1899 Lead, pacemaker/cardioverter-defibrillator combination (implantable)
C2619 Pacemaker, dual chamber, nonrate-responsive (implantable)
C2620 Pacemaker, single chamber, nonrate-responsive (implantable)
C2621 Pacemaker, other than single or dual chamber (implantable)
G0448 Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

ICD-9-CM Procedure Codes
00.50 Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system [CRT-P]
00.51 Implantation of cardiac resynchronization defibrillator, total system [CRT-D]
00.52 Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system
00.53 Implantation or replacement of cardiac resynchronization pacemaker, pulse generator only [CRT-P]
00.54 Implantation or replacement of cardiac resynchronization defibrillator, pulse generator device only [CRT-D]
37.74 Insertion or replacement of epicardial lead [electrode] into epicardium
37.75 Revision of lead [electrode]
37.79 Revision or relocation of cardiac device pocket
37.80 Insertion of permanent pacemaker, initial or replacement, type of device not specified
37.81 Initial insertion of single-chamber device, not specified as rate responsive
37.82 Initial insertion of single-chamber device, rate responsive
37.83 Initial insertion of dual-chamber device
37.85 Replacement of any type pacemaker device with single-chamber device, not specified as rate responsive
37.86 Replacement of any type pacemaker device with single-chamber device, rate responsive
37.87 Replacement of any type pacemaker device with dual-chamber device
37.89 Revision or removal of pacemaker device
37.97 Replacement of automatic cardioverter-defibrillator lead(s) only
37.98 Replacement of automatic cardioverter defibrillator pulse generator only

ICD-9-CM Diagnosis Codes
412 Old Myocardial Infarction
414.8 Other specified forms of chronic ischemic heart disease

Clinical Coverage Guideline

INTERNAL CARDIAC DEFIBRILLATORS AND PACEMAKERS FOR PREVENTION OF SUDDEN DEATH
HS-199

425.11 Hypertrophic cardiomyopathy (obstructive)
425.18 Hypertrophic cardiomyopathy (nonobstructive)
425.3 Congenital cardiomyopathy
425.4 Other primary Cardiomyopathies
426.82 Long QT Syndrome
427.0 Paroxysmal supraventricular tachycardia (sustained)
427.1 Paroxysmal ventricular tachycardia (sustained)
427.2 Paroxysmal tachycardia, unspecified (sustained) (nonsustained)
427.41 Ventricular fibrillation
746.84 Congenital hypertrophic cardiomyopathy (obstructive)
746.89 Brugada syndrome
V12.53 Sudden cardiac arrest successfully resuscitated

Non-covered ICD-9-CM Diagnosis Codes
410.00 - 410.92 Acute myocardial infarction (less than 8 weeks / 40 days old)

Draft ICD-10-PCS (Inpatient Only)
Refer to the following ICD-10-PCS tables for specific code assignment based on physician documentation.
NOTE: Per ICD-10-PCS Coding Guidelines, “ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code”.

02H Medical and Surgical, Heart & Great Vessels, Insertion
02W Medical and Surgical, Heart & Great Vessels, Revision
0JH Medical and Surgical, Subcutaneous Tissue & Fascia, Insertion
0JP Medical and Surgical, Subcutaneous Tissue & Fascia, Removal
0JW Medical and Surgical, Subcutaneous Tissue & Fascia, Revision

Draft Covered ICD-10-CM Diagnosis Codes
I25.2 Old myocardial infarction
I25.5 Ischemic cardiomyopathy
I25.89 Other forms of chronic ischemic heart disease
I25.9 Chronic ischemic heart disease, unspecified
I42.0 Dilated cardiomyopathy
I42.1 Obstructive hypertrophic cardiomyopathy
I42.2 Other hypertrophic cardiomyopathy
I42.4 Endocardial fibroelastosis
I42.5 Other restrictive cardiomyopathy
I42.8 Other cardiomyopathies
I42.9 Cardiomyopathy, unspecified
I45.81 Long QT time
I47.0 - I47.9 Ventricular arrhythmia
I49.01 - I49.2 Junctional premature depolarization, ventricular fibrillation
Q23.8 Other congenital malformations of aortic and mitral valves
Q23.9 Congenital malformation of aortic and mitral valves, unspecified
Q24.8 Other specified congenital malformations of heart
Z86.74 Personal history of sudden cardiac arrest; successfully resuscitated

Draft Non-Covered ICD-10-CM Diagnosis Codes
I21.01 - I21.3 ST Elevation (STEMI) myocardial infarction;
(with a stated duration of 4 weeks or /28 days or less from onset)
I21.4 Non-ST elevation (NSTEMI) myocardial infarction
(with a stated duration of 4 weeks or /28 days or less from onset)
I22.0 - I22.9 Subsequent ST and Non-ST elevation (STEMI)(NSTEMI) myocardial infarction (occurring within 4 weeks/28 days of a previous acute myocardial infarction)


REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>3/5/2015, 3/6/2014</td>
<td>• Approved by MPC. No changes.</td>
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<tr>
<td>4/4/2013</td>
<td>• Approved by MPC. New guideline.</td>
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