



CARDIOVERTER DEFIBRILLATORS

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I. DESCRIPTION

Cardiovascular disease is the single most common cause of death in the United States. There are 250,000 out-of-hospital cardiac arrests per year with a 95% mortality for these patients. This extremely low survival rate has motivated the prophylactic implantation of defibrillators as a means of primary prevention (American Heart Association, January 2004).

Sudden cardiac death (SCD) claims 400,000 individuals in the United States annually. Most adult deaths due to SCD stem from coronary artery disease. Childhood and adolescent deaths due to SCD range from 1 to 8 per 100,000. Nearly half of all sudden deaths in previously healthy children had no abnormal findings on routine autopsy. It can now be shown on molecular autopsy that probes the genes, that some fatal arrhythmias arise secondary to a primary channelopathy. The cardiac channelopathies comprise a class of primary inherited arrhythmia syndromes that stem from defective ion channels in the heart. The symptoms are syncope, seizures, or sudden death. These channelopathies include long QT syndrome (LQTS), Brugada syndrome (BrS), progressive cardiac conduction disease or familial atrio-ventricular conduction block, catecholeminergic polymorphic ventricular tachycardia (CPVT), idiopathic ventricular fibrillation, and a small percentage of sudden infant death syndrome.

Approximately five (5) million people in the United States have heart failure and over 550,000 are diagnosed annually for the first time. Heart failure is the primary reason for 12 to 15 million-office visits each year. It has been reported that more than 500,000 individuals in the United States have permanently implanted pacemakers or ICDs with 115,000 new devices implanted each year. Heart disease is the leading cause of death in the United States and Michigan. For the year 2005, heart disease accounted for 27% of total deaths in the United States. Approximately 25,000 Michigan residents died of heart disease in 2004.

The implantable cardioverter defibrillator (ICD) is an electronic device that is implanted in patients identified at high risk for sudden cardiac death (SCD) due to ventricular tachyarrhythmia, i.e., ventricular tachycardia (VT) and ventricular fibrillation (VF). The ICD continuously monitors heart rhythm, automatically senses malignant tachyarrhythmia and aborts VT/VF by means of overdrive pacing or a transcardial electrical countershock, which restores normal rhythm.



The ICD has two components: a pulse generator and defibrillator lead(s). The pulse generator contains a battery and circuitry that provides a variety of functions: generating energy and delivering defibrillating shocks, filtering/analyzing, and storing electrical signals from the myocardium to distinguish normal from pathologic rhythms that require a response from the ICD.

Multiple clinical trials of ICDs have been performed in recent years to assess which patients would benefit from ICD therapy. The clinical trials have generally been of two types: secondary prevention (involving patients resuscitated after cardiac arrest or unstable ventricular tachycardia) and primary prevention (involving patients at increased risk for sudden cardiac death but without documented history of cardiac arrest or unstable ventricular tachycardia). The indications for ICD therapy have changed several times in recent years, as various clinical trial results became available. Further changes may occur in the coming years as additional experience with these devices is accumulated.

II. POLICY/CRITERIA

- A. **Implantable Cardioverter Defibrillators (ICDs)** are covered consistent with the recommendations for Class I and Class IIa indications found in the ACC/AHA/HRS Guidelines for Device-Based Therapy, June 2008. Guidelines are available @ <http://content.onlinejacc.org/cgi/content/full/j.jacc.2008.02.032>

ICDs must be prior authorized by Priority Health. Patients must be on optimal medical therapy, have a reasonable expectation of survival with good functional status for more than 1 year, **and** meet **one** of the following criteria for adults:

1. Survivors of cardiac arrest due to ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT) after evaluation to define the cause of the event and to exclude any completely reversible causes. (*Class I*)
2. Left ventricular dysfunction with prior MI (Ischemic Cardiomyopathy) and one of the following:
 - a. LVEF less than 35% due to prior MI who are at least 40 days post-myocardial infarction and who are in NYHA functional Class II or III. (*Class I*)
 - b. LVEF less than 30%, at least 40 days post-myocardial infarction, and are in NYHA functional Class I. (*Class I*)
 - c. nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study. (*Class I*)



3. Nonischemic dilated cardiomyopathy with an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. (*Class I*)
4. Syncope of undetermined origin and one of the following:
 - a. clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study. (*Class I*)
 - b. significant LV dysfunction, and nonischemic dilated cardiomyopathy. (*Class IIa*)
5. Ventricular Tachycardia and one of the following:
 - a. structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. (*Class I*)
 - b. sustained VT and normal or near normal ventricular function. (*Class IIa*)
6. Familial or inherited conditions: one of the following:
 - a. hypertrophic cardiomyopathy (HCM) with 1 or more of the following major risk factors for sudden cardiac death (SCD) (*Class IIa*):
 - i. prior cardiac arrest
 - ii. spontaneous sustained VT
 - iii. spontaneous nonsustained VT
 - iv. family history of SCD
 - v. syncope
 - vi. LV thickness greater than or equal to 30 mm
 - vii. abnormal blood pressure response to exercise
 - b. prevention of SCD in patients with arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) who have 1 or more of the following risk factors for SCD. (*Class IIa*)
 - i. induction of VT during electrophysiological testing
 - ii. detection of nonsustained VT on noninvasive testing
 - iii. male gender
 - iv. severe right ventricular (RV) dilation
 - v. extensive RV involvement
 - vi. young age at presentation (less than 5 years)
 - vii. LV involvement
 - viii. prior cardiac arrest
 - ix. unexplained syncope
 - x. deleterious genetic mutations associated with ARVD/C
 - c. To reduce SCD in patients with long-QT syndrome who are experiencing syncope and/or VT while receiving beta blockers. (*Class IIa*)



- d. For patients with Brugada syndrome who have had syncope. (*Class IIa*)
 - e. For patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest. (*Class IIa*)
 - f. For patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers. (*Class IIa*)
7. Non hospitalized patients awaiting heart transplantation (*Class IIa*)
 8. Cardiac sarcoidosis (*Class IIa*)
 9. Giant cell myocarditis (*Class IIa*)
 10. Chagas disease (*Class IIa*)

Indications 2 & 3 must also meet the following criteria:

- a. Patients must be able to give informed consent; Priority Health's Decision Support Tool is required for criteria 2 & 3 above
 - b. Ejection fractions must be measured by angiography, radionuclide scanning, echocardiography, or MRI.
 - c. 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 Infarction¹
- B. The following Class I and Class IIa ICD indications are covered for pediatric patients and patients with congenital heart disease. One of the following:
1. Survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes. (*Class I*)
 2. Patients with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation. Catheter ablation or surgical repair may offer possible alternatives in carefully selected patients. (*Class I*)
 3. Patients with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study. (*Class IIa*)
- C. Use of Microvolt T-Wave Alternans (MTWA) testing in conjunction with patient history, physical exam and other diagnostic information as a tool for risk stratification for sudden cardiac death in patients with ventricular arrhythmias is a covered benefit. The use of this testing is endorsed by the American College of Cardiology and the American Heart Association and is included as a recommendation in their practice guidelines.



- D. ICDs are considered experimental and **not a covered benefit** for any indication other than Class I and IIa indications listed above. ICDs are also not covered if any of the following is present:
1. Irreversible brain damage, disease or dysfunction that precludes the ability to give informed consent.
 2. Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure, advanced cerebrovascular disease), associated with a likelihood of survival less than 1 year.
 3. Member has asymptomatic VT or symptomatic VT/VF that is
 - a. associated with acute myocardial infarction within 2 days,
 - b. due to a remediable cause,
 - c. controlled by appropriate drug therapy, and
 - d. amenable to definitive therapy (e.g., ablative procedures, surgery);
 4. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm.
 5. Had a CABG or PTCA within the past 3 months.
 6. Had an acute MI within the past 40 days.
 7. Clinical symptoms or findings that would make them a candidate for coronary revascularization.
 8. For primary prevention of SCD in members with NYHA Class IV drug-refractory congestive heart failure.
 9. The planned ICD has not received full market approval from the FDA.
- E. Biventricular Pacemakers (Cardiac Resynchronization Therapy)/Combination Resynchronization-Defibrillation Devices for Congestive Heart Failure, alone or in combination with an AICD(CRT/AICD) may be covered when **all** of the following are met:
1. Device is FDA approved
 2. Patient has NYHA Class III or IV
 3. LVEF \leq .35
 4. QRS duration \geq 120 msec
 5. Patient is on appropriate pharmacological regimen prior to implant, unless contraindicated

Review of data on expanded indications for CRT/ICD at Technology Assessment Committee December 2009: Results of published trials (MADIT-CRT & REVERSE) on use of CRT/ICD in NYHA Class I & II are available (Moss, et. al.; St. John Sutton, et. al.; Linde, et. al.). Currently no devices have FDA approval for NYHA Class I & II. In subgroup analysis for class I & II HF, the greatest benefit, including a reduction in HF admissions, for CRT/ICD was in class II HF with a QRS >150 msec. There was no mortality benefit in either trial. Trials continue on the use of CRT/ICD for class I & II HF.



- F. ¹Criteria for acute, evolving, or recent MI (Alpert and Thygesen et al., 2000). Either one of the following criteria satisfies the diagnosis for 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.
- G. Criteria for established MI. Any one of the following criteria satisfied 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.

The New York Heart Association Classification:

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|-------------------|---|
| Class I: | Patients 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: | Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity (e.g., moderate physical exertion such as carrying shopping bags up several flights or stairs) results in fatigue, palpitation, dyspnea, or anginal pain. |
| Class III: | Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity (i.e., mild exertion) causes fatigue, palpitation, dyspnea, or anginal pain. |
| Class IV | Patients with cardiac disease resulting in 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. |



- H. **Wearable Cardioverter Defibrillators** may be covered under the DME benefit when Interqual criteria are met.
- I. **Automatic External Defibrillators (AEDs)** in the public setting or in the home are not a covered benefit. AEDs are classified as precautionary safety devices. Compared to conventional resuscitation, in-home availability of AEDs did not improve survival when studied in post MI patients (Bardy, GH. et. al.).

III. MEDICAL NECESSITY REVIEW

- Required Not Required Not Applicable

IV. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *Coverage is determined by the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html.*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

Coverage for Medicare Members — This policy does not apply to Medicare members. National Coverage Determination is available for Medicare members.

V. CODING INFORMATION

ICD-9 Codes that may support medical necessity

- 086.0 Chagas' disease with heart involvement
- 402.01 Malignant hypertensive heart disease with heart failure
- 402.11 Benign hypertensive heart disease with heart failure
- 402.91 Unspecified hypertensive heart disease with heart failure
- 410.0 – 410.9 Acute myocardial infarction
- 412 Old myocardial infarction



- 414.8 Other forms of chronic ischemic heart disease
- 422.91 Idiopathic myocarditis
- 425.1 Hypertensive obstructive cardiomyopathy
- 425.4 Other primary cardiomyopathies
- 425.8 Cardiomyopathy in other diseases classified
- 427.0 Paroxysmal supraventricular tachycardia
- 427.1 Paroxysmal ventricular tachycardia
- 427.2 Paroxysmal tachycardia, unspecified
- 427.41 Ventricular fibrillation
- 427.42 Ventricular flutter
- 427.5 Cardiac arrest
- 427.89 Other specified cardiac dysrhythmias
- 427.9 Cardiac dysrhythmia, unspecified
- 428.0-428.9 Heart failure
- 746.89 Other specified anomalies of heart
- 780.2 Syncope and collapse
- 996.04 Mechanical complication of cardiac device, implant, and graft due to automatic implantable cardiac defibrillator
- 996.61 Infection and inflammatory reaction due to cardiac device, implant, and graft
- 996.72 Other complications of internal prosthetic device, implant, and graft due to other cardiac device, implant, and graft
- V45.02 Automatic implantable cardiac defibrillator
- V53.32 Fitting and adjustment of other device, automatic implantable cardiac defibrillator

CPT/HCPCS CodesInsertion

- 33202 Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)
 - 33203 Insertion of epicardial electrode(s); endoscopic approach (e.g., thoracoscopy, pericardioscopy)
 - 33216 Insertion of a transvenous electrode; single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator
 - 33217 Insertion of a transvenous electrode; dual chamber (two electrodes) permanent pacemaker or dual chamber pacing 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 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 (including upgrade to dual chamber system) (List separately in addition to code for primary procedure)
 - C1777 Lead, cardioverter-defibrillator, endocardial single coil (implantable)
 - C1895 Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
 - C1896 Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
 - C1899 Lead, pacemaker/cardioverter-defibrillator combination (implantable)
- (The above codes do not require prior authorization)*



- 33240 Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator
- 33249 Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter and insertion of pulse generator

Device

These codes should be billed by the service facility with revenue codes 0272, 0275, or 0278.

- C1721 Cardioverter-defibrillator, dual chamber (implantable)
- C1722 Cardioverter-defibrillator, single chamber (implantable)
- C1882 Cardioverter-defibrillator, other than single or dual chamber (implantable)

Portable Device

- K0606 Automatic external defibrillator, with integrated electrocardiogram analysis, garment type

Removal/Revision/Repair/Electrophysiologic Services

Prior authorization not required for the following services:

- 33215 Repositioning of previously implanted transvenous pacemaker or pacing cardioverter-defibrillator (right atrial or right ventricular) electrode
- 33218 Repair of single transvenous electrode for a single chamber, permanent pacemaker or single chamber pacing cardioverter-defibrillator
- 33220 Repair of two transvenous electrodes for a dual chamber permanent pacemaker or dual chamber pacing cardioverter-defibrillator
- 33223 Revision of skin pocket for single or dual chamber pacing cardioverter-defibrillator
- 33241 Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator
- 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
- 93640 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;
- 93641 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
- 93642 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
- 93282 Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; single lead implantable cardioverter-defibrillator system



- 93283 Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; dual lead implantable cardioverter-defibrillator system
- 92384 Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; multiple lead implantable cardioverter-defibrillator system
- 93287 Peri-procedural device evaluation and programming of device system parameters before or after a surgery, procedure, or test with physician analysis, review and report; single, dual, or multiple lead implantable cardioverter-defibrillator system
- 93289 Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead implantable cardioverter-defibrillator system, including analysis of heart rhythm derived data elements
- 93292 Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
- 93295 Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable cardioverter-defibrillator system with interim physician analysis, review(s) and report(s)
- 93296 Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system or implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

Not covered:

E0617 External defibrillator with integrated electrocardiogram analysis

Special Notes: Priority Health's Technology Assessment Committee reviewed ICDs on March 5, 2004 and June 3, 2005 and recommended coverage per the criteria listed in this policy.

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Group Cardiac Resynchronization Induces Major Structural and Functional Reverse Remodeling in Patients With New York Heart Association Class I/II Heart Failure Circulation, Nov 2009; 120: 1858 - 1865.

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Randomized trial of cardiac resynchronization in mildly symptomatic heart failure patients and in asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. Cecilia Linde, et. al. and REVERSE (REsynchronization reVERses Remodeling in Systolic left vEntricular dysfunction) Study Group *J Am Coll Cardiol.* 2008 December 2; 52(23): 1834–1843.

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