PriorityHealth

MEDICAL POLICY
No. 91410-R15

CARDIOVERTER DEFIBRILLATORS

Effective Date: February 20, 2017	**Review Dates: 1/93, 12/94, 12/99, 12/01, 2/02, 1/03, 1/04, 4/04, 3/05, 8/05, 6/06, 10/06, 7/07, 6/08, 8/08, 8/09, 8/10, 8/11, 8/12, 8/13, 8/14, 8/15, 8/16, 8/17, 8/18**
Date Of Origin: December 31, 1991	**Status: Current**

I. POLICY/CRITERIA

Cardioverter Defibrillators for Adults

A. Implantable Cardioverter Defibrillators (ICDs) and **Cardiac Resynchronization Therapy (Biventricular Pacemakers)**/Combination Resynchronization-Defibrillation Devices, alone or in combination with an AICD (CRT/AICD) are covered according to InterQual® criteria and must be prior authorized by Priority Health.

In addition to meeting InterQual®criteria, patient has completed the Emmi Defib (Implantable Cardioverter Defibrillator-ICD) pre-surgical decision support tool prior to requesting authorization.

B. ICDs are considered experimental and **not a covered benefit** for any indication not addressed by InterQual®.

C. **ICD/CRT replacement**. The following are recommendations for improving decisions surrounding ICD/CRT replacement, including generator replacement (Kramer, D., Buxton, A., Zimetbaum, P., 2012).

1. A comprehensive medical evaluation should occur before ICD/CRT replacement, with direct communication between the implanting physician and primary care physician, as well as other specialists involved in each patient's care.
2. Patient preferences, past experiences, and advance care planning should be explicitly included in decision making.
3. Advance care planning should be revisited and patients should be educated about the possibility of device deactivation at the time of potential ICD/CRT replacement.

Cardioverter Defibrillators – Pediatric Patients

A. The following Class I and Class IIa ICD indications are covered for pediatric patients and patients with congenital heart disease who meet one of the following criteria:

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

electrophysiologicalevaluation. 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)*

Wearable Cardioverter Defibrillators
May be covered under the DME benefit when InterQual® criteria are met.

Automatic External Defibrillators (AEDs) in the public setting or in the home are not a covered benefit. Compared to conventional resuscitation, in-home availability of AEDs did not improve survival when studied in post MI patients (Bardy, GH. et. al.). There is insufficient evidence to assess safety or impact on long-term outcomes in pediatric patients with congenital long QT syndrome.

Microvolt T-Wave Alternans (MTWA) testing
Use 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.

II. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required ☐ Not Applicable

III. 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. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **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); if a coverage determination has not been adopted by CMS, this policy applies.***

- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

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

IV. 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.

Cardiac resynchronization therapy (CRT) is a form of cardiac pacing used as a treatment for patients with chronic, medically refractory heart failure associated with interventricular asynchrony. This therapy evolved from existing cardiac pacing technology and is based on the earliest studies of the acute hemodynamic results of biventricular pacing. Since patients with ventricular pacemakers exhibited dyssynchronous ventricular contraction and paradoxical septal motion, dual-chambered (atrioventricular) pacemakers did little to improve the cardiac function of patients with heart failure and dilated cardiomyopathy. Stimulating both ventricles simultaneously in order to optimize septal motion and ventricular efficiency was initially accomplished in patients who had undergone cardiac surgery. Epicardial leads allowed acute biventricular pacing for these patients, and produced an improvement in cardiac function CRT and implantable cardioverter defibrillator (ICD) therapy can be combined in a single device.

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.). 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.

In September of 2010 the FDA approved Boston Scientific CRT for "Left bundle bunch block with QRS ≥ 130ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure". Post-approval studies are required.

V. CODING INFORMATION

ICD-10 Codes that may apply:

A18.84	Tuberculosis of heart
B57.0 – B57.2	Chagas' disease with/without heart involvement
D86.85	Sarcoid myocarditis
I11.0	Hypertensive heart disease with heart failure
I21.01 - I21.4	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I22.0 – I21.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I25.2	Old myocardial infarction
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I40.0 – I40.9	Acute myocarditis
I42.0 – I42.9	Cardiomyopathy
I43	Cardiomyopathy in diseases classified elsewhere
I45.6	Pre-excitation syndrome
I45.81	Long QT syndrome
I45.89	Other specified conduction disorders
I46.2 – I46.9	Cardiac arrest
I47.0 – I47.9	Paroxysmal tachycardia
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I49.2	Junctional premature depolarization
I49.3	Ventricular premature depolarization
I49.8	Other specified cardiac arrhythmias
I49.9	Cardiac arrhythmia, unspecified
I50.1 – I50.9	Heart failure
Q24.8	Other specified congenital malformations of heart
R00.1	Bradycardia, unspecified
R55	Syncope and collapse
T82.110A – T82.119S	Mechanical complication of cardiac electronic device
T82.120A – T82.129S	Displacement of cardiac electronic device
T82.190A - T82.199S	Other mechanical complication of cardiac electronic device

T82.7xxA - T82.7xxS	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts
T82.817A – T82.898S	Other specified complications of cardiac and vascular prosthetic devices, implants and grafts
T82.9xxA - T82.9xxS	Unspecified complication of cardiac and vascular prosthetic device, implant and graft
Z45.02	Encounter for adjustment and management of automatic implantable cardiac defibrillator
Z82.41	Family history of sudden cardiac death
Z86.74	Personal history of sudden cardiac arrest
Z95.810	Presence of automatic (implantable) cardiac defibrillator

CPT/HCPCS Codes

Insertion

Prior authorization not required for the following services:

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 implantable defibrillator
33217	Insertion of 2 transvenous electrodes; permanent pacemaker or implantable defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable 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 implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33271	Insertion of subcutaneous implantable defibrillator electrode

*Prior authorization **REQUIRED***:

33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system

33264 Removal of pacing implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system

33270 Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed

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 (*Payable to Ambulatory Surgical Center only)*

Device

*Prior authorization **REQUIRED**:*

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)

Ancillary Codes

Prior authorization not required for the following:

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)

Wearable Device

*Prior authorization **REQUIRED**:*

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

K0607 Replacement battery for automated external defibrillator, garment type only, each
K0608 Replacement garment for use with automated external defibrillator, each
K0609 Replacement electrodes for use with automated external defibrillator, garment type only, each

Removal/Revision/Repair/Electrophysiologic Services

Prior authorization not required for the following services:

33215 Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode
33218 Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator
33220 Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator

33223 Relocation of skin pocket for implantable defibrillator
33224 Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of generator

33241 Removal of implantable defibrillator pulse generator only
33243 Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy
33244 Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction

93025 Microvolt T-wave alternans for assessment of ventricular arrhythmias

Programming Services
Prior authorization not required for the following services:
93260 Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system
93261 Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system

93282 Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with p analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system
93283 Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system
93284 Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system

93287 Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system

93289 Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional,, 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 analysis, review and report by a physician or other qualified health care professional, 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 analysis, review(s) and report(s) by a physician or other qualified health care professional

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

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)

93644 Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

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.

VI. REFERENCES

"Automatic Defibrillators, Implanted" HAYES, Inc. October 2000 and Updated search September 2003.

Bansch D, Antz M, Boczor S, et al. Primary prevention of sudden death in idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). Circulation 2002;105:1453-8.

Bigger JT Jr. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. N Engl J Med 1997;337:1569-75.

"Cardioverter-Defibrillators", Aetna Clinical Policy Bulletins Number: 0585 Available on the World Wide Web at: http://www.aetna.com/cpb/data/CPBA0585.html (Retrieved February 9, 2004 , July 9, 2009 & July 22, 2011)

http://www.aetna.com/cpb/medical/data/500_599/0585.html (Retrieved May 29, 2018)

Connolly SJ, Gent M, Roberts RS, et al. Canadian Implantable Defibrillator Study (CIDS). Circulation 2000;101:1297-302

DiMarco JP, Implantable Cardioverter-Defibrillators. N Engl J Med 2003;349;19:1836-1847.

Gregorates, G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky MA, et al. ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac pacemakers and Antiarrhythmia Devices: Summary Article. Circulation 2002;106:2145-2161.

Kuck et al. The Cardiac Arrest Study Hamburg (CASH), St. Georg Hospital, Hamburg, Germany. Circulation 2000;102:748-54.

Medicare Coverage Policies, WPS Available on the World Wide Web at http://www.wpsic.com/medicare/policies/illinois/cv14.shtml (Retrieved February 9, 2004)

Moss AJ, et al. Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction. N Engl J Med 2002;346:877-83

Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implantable defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. N Engl J Med 1996;335:1933-40.

The Antiarrhythmic versus Implantable Defibrillators (AVID) Investigators. N Engl J Med 1997;337:1576-83.

Implementation for Implantable Defibrillators (CAG-00157R3), Centers for Medicare & Medicaid Services, 1/27/2005. Available on the World Wide Web @ https://www.cms.hhs.gov/mcd/1#1 (Retrieved 2/15/05)

Alpert , Thygesen, et. al., Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction; 2000.

"Biventricular Pacing" Aetna Clinical Policy Bulletin, October 12, 2004. Available on the World Wide Web @ http://www.aetna.com/cpb/data/CPBA0610.html (Retrieved July 6, 2005)

http://www.aetna.com/cpb/medical/data/600_699/0610.html (Retrieved May 29, 2017)

"Biventricular Pacemakers for the Treatment of Congestive Heart Failure" The Regence Group Medical Policy, October 7, 2003. Available on the World Wide Web @ http://www.regence.com/printFriendly.jsp (Retrieved July 6, 2005)

Gould, P.A. and Krahn, A. D. "Complications Associated with Implantable Cardioverter-Defibrillator Replacement in Response to Device Advisories". JAMA, April 26, 2006. Vol 295, No 16. 1907-11.

Maisel, W. H., et. al. "Pacemaker and ICD Generator Malfunctions: Analysis of Food and Drug Administration Annual Reports". JAMA, April 26, 2006. Vol 295, No 16. 1901-06.

Maisel, W. H. "Pacemaker and ICD Generator Reliability: Meta-analysis of Device Registries". JAMA, April 26, 2006. Vol 295, No 16 1929-34.

Hayes directory: Microvolt T-Wave Alternans to Identify Risk of Ventricular Arrhythmias and Sudden cardiac death – March 2004; updated May 2006; Accessed august 2006

Chan, PS et al. Cost Effectiveness of Microvolt T-wave alternans screening strategy for implantable cardioverter-defibrillator placement in the MADIT-II eligible population. J Am Coll Cardiol. July 2006; 48(1): 112-21

Chow, T et al. Prognostic utility of microvolt T-wave alternans in risk stratification of patients with ischemic cardiomyopathy. J Am Coll Cardiol May 2006; 47(9): 1820-1827

Armoundas, AA et al. Can microvolt T-wave alternans testing reduce unnecessary defibrillator implantation? Nature Clinical Practice October 2005: 2(10): 522-528

Lam SKH, Owen A. Combined Resynchronisation and Implantable Defibrillator Therapy in Left Ventricular Dysfunction: Bayesian Network Meta-analysis of Randomised Controlled Trials. BMJ. 2007 Nov 3.

Beshai JF, Grimm RA, Nagueh SF, et al. Cardiac-resynchronization therapy in heart failure with narrow QRS complexes. N Engl J Med. 2007 Nov 6.

Bardy GH, Lee KL, Mark DB, et al. Home use of automated external defibrillators for sudden cardiac arrest. N Engl M Med. 2008 Apr 1;

National Institutes of Health (NIH) [website]. Automated External Defibrillators and CPR Are Equally Helpful for Sudden Cardiac Arrest in the Home. NIH News. April 1, 2008. Available at: http://www.nih.gov/news/health/apr2008/nhlbi-01.htm.

Ezekowitz, J. A., et. al. Systematic review: Implantable cardioverter defibrillators for adults with left ventricular systolic dysfunction. Ann Intern Med. 2007;147:252-262

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities J Am Coll Cardiol, 2008; 51:1-62, doi:10.1016/j.jacc.2008.02.032 Available @http://content.onlinejacc.org/cgi/content/full/j.jacc.2008.02.032

Cardiac Resynchronization Therapy/Implantable Cardioverter Defibrillator (CRT/ICD), Expanded Indication, Hayes Prognosis Report, Sept. 2009

Moss AJ, Hall WJ, Cannom DS, et al. Cardiac-Resynchronization Therapy for the Prevention of Heart-Failure Events. N Engl J Med. September 1, 2009.

MADIT-CRT: Automatic Defibrillator Implantation With Cardiac Resynchronization Therapy. Available at: http://www.clinicaltrials.gov/ct2/show/NCT00180271

Martin St. John Sutton, Stefano Ghio, Ted Plappert, Luigi Tavazzi, Laura Scelsi, Claude Daubert, William T. Abraham, Michael R. Gold, Christian Hassager, John M. Herre, Cecilia Linde on Behalf of the REsynchronization reVErses Remodeling in Systolic left vEntricular dysfunction (REVERSE) Study 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.

Resynchronization reVErses Remodeling in Systolic Left vEntricular Dysfunction (REVERSE) Available at http://clinicaltrials.gov/ct2/show/study/NCT00271154?term=NCT00271154&rank=1

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.

Hayes, Inc. Cardiac Resynchronization Therapy for Heart Failure April 16, 2008 & annual updates.

Sipahi, I., Carrigan, P. et. al.Impact of QRS Duration on Clinical Event Reduction With Cardiac Resynchronization Therapy:Meta-analysis of Randomized Controlled Trials Arch Intern Med. Published online June 13, 2011. doi:10.1001/archinternmed.2011.247

Kramer DB, Buxton AE, Zimetbaum PJ. Time for a change--a new approach to ICD replacement. N Engl J Med. 2012 Jan 26;366(4):291-3.

Allen LA, Stevenson LW, Grady KL, Goldstein NE, Matlock DD, Arnold RM, Cook NR, Felker GM, Francis GS, Hauptman PJ, Havranek EP, Krumholz HM, Mancini D, Riegel B, Spertus JA; American Heart Association; Council on Quality of Care and Outcomes Research; Council on Cardiovascular Nursing; Council on Clinical Cardiology; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Surgery and Anesthesia. Decision making in advanced heart failure: a

scientific statement from the American Heart Association. Circulation. 2012 Apr17;125(15):1928-52.

2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society Journal of the American College of Cardiology Vol. 61, No. 3, 2013@ http://content.onlinejacc.org/solr/searchresults.aspx?q=device%20guideline&fd_JournalID=101&f_JournalDisplayName=Journal%20of%20the%20American%20College%20of%20Cardiology&SearchSourceType=3

Goldenberg I et al. Survival with cardiac-resynchronization therapy in mild heart failure. N Engl J Med 2014 Mar 30.

Hayes, Inc. Home Use of Automated External Defibrillator in Pediatric Patients with Congenital Long QT Syndrome, January 19, 2017