Clinical Policy Title: Wearable cardioverter - defibrillators

Clinical Policy Number: 04.02.01

Effective Date: September 1, 2013
Initial Review Date: December 10, 2013
Most Recent Review Date: February 6, 2018
Next Review Date: February 2019

Related policies:

CP# 04.03.04 Home use of non-wearable automatic external defibrillator

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of wearable cardioverter-defibrillators (also LifeVest) to be clinically proven and therefore, medically necessary when the following criteria are met for members:

- Meets American College of Cardiology (ACC), American Heart Association (AHA) and Health Reimbursement Accounts’ (HRS) criteria for placement of an implantable cardioverter defibrillator, including but not limited to members who have documented evidence of ventricular fibrillation or non-sustained ventricular tachycardia lasting >= 30 seconds, and ejection fraction of 35 percent or less, or of documented ventricular fibrillation. (See ACC/AHR/HRS Guidelines [a and b] in the Background section below for those Class I and Class II indications, where the benefits are much greater than the risks); AND

- Has contraindication to immediate implantable cardioverter defibrillator placement such as anticipated heart transplantation, infection preventing implantable cardioverter defibrillator placement, implantable cardioverter defibrillator re-implantation delay because of infection, mural thrombus, or acute myocardial infarction with tachycardia; AND
• Has transient or reversible causes excluded such as acute myocarditis, electrolyte imbalance or an arrhythmia not amenable to medical therapy or ablation; AND
• Meets ACC/AHR/HRS criteria for an implantable cardioverter defibrillator but has a short-term risk, such as waiting list for cardiac transplantation; AND
• Anticipated duration of coverage is three months unless there is a reasonable explanation presented; AND
• Age is 18 years or older (Epstein, 2008p; Tracy, 2012).

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of wearable cardioverter-defibrillators are not medically necessary.

- Coverage is a bridge to permanent implantable cardioverter defibrillator beyond three months, unless there is a medically valid reason for an extension of intended implantable cardioverter defibrillator placement.
- Contraindications include but are not limited to the following circumstances:
  - Inability or refusal to wear the wearable cardioverter-defibrillator continuously. Dressing or personal hygiene are appropriate reasons for removing the wearable cardioverter-defibrillator, but failure to wear the device because of intolerance to the bulk of the wearable cardioverter-defibrillator makes the device ineffective.
  - Member is in hospice care or has a “do not resuscitate” status, unless there is documentation of patient preference for treatment of cardiac arrhythmias, with use of the wearable cardioverter-defibrillator.
  - Member is pregnant or nursing.
  - Member is not able to respond to treatment alarms so may be subject to unnecessary electrical shocks.
  - Member has excessive exposure to electromagnetic interference.
  - Use beyond the indications listed above is considered not medically necessary and investigational. As such, unlisted indications are not covered benefits.

Alternative covered services:

- Implanted Cardiac Defibrillator
- Cardiac medications

Background
Sudden cardiac death is a frequent cause of unanticipated demise. Nearly 300,000 people die each year outside of the hospital setting as a result of sudden cardiac death. The cause of sudden cardiac death is felt to be from a lethal ventricular arrhythmia, primarily ventricular fibrillation. Implantable cardioverter defibrillators have been used for several decades as a therapeutic strategy to detect VF and respond with a counter-shock, to restore normal rhythm. The use of implantable cardioverter defibrillators is felt to have prevented deaths from ventricular fibrillation, because of the rapid restoration of normal sinus rhythm. Studies have demonstrated a 97 percent survival rate if normal rhythm is restored within one minute, but that survival rate drops to five percent if normal rhythm is not restored until 10 minutes. Implanted implantable cardioverter defibrillators have been demonstrated to reduce this death rate (Riwald, 2014).

The wearable cardioverter-defibrillator (also LifeVest developed by Lifecor Inc. and acquired by Zoll Medical Corp) is designed to serve the same function as an implantable cardioverter defibrillator, but is an external, non-invasive vest with a cardiac sensor and the capacity to either cardiovert an abnormal rhythm with a low electrical current, or defibrillate with a higher current electrical shock. Studies of the LifeVest have been retrospective and derived from registry information. There are no randomized controlled clinical trials. One study reported on registry data demonstrating >90 percent compliance with use of the wearable cardioverter-defibrillator. However, those who did not wear the vest according to study requirements complained about the weight and bulk of the device (Chung, 2013). Additionally, the experience in the short run has been positive with low complication rates, but there is no long-term experience.

American College of Cardiology (ACC)/American Heart Association (AHA)/Health Reimbursement Accounts (HRA) guidelines for device-based therapy (Epstein, 2008; Tracy, 2012)

<table>
<thead>
<tr>
<th>Indications with Class I evidence</th>
<th>Indications with Class II evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ICD therapy is indicated in patients who are survivors of cardiac arrest due to VF, or hemodynamically unstable sustained ventricular tachycardia (VT) after evaluation to define the cause of the event, and to exclude any completely reversible causes. <em>(Level of Evidence: A)</em>.</td>
<td>1. ICD implantation is reasonable for patients with unexplained syncope, significant left ventricular dysfunction (LVD), and nonischemic dilated cardiomyopathy. <em>(Level of Evidence: C).</em></td>
</tr>
<tr>
<td>2. ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. <em>(Level of Evidence: B).</em></td>
<td>2. ICD implantation is reasonable for patients with sustained VT and normal or near-normal ventricular function. <em>(Level of Evidence: C).</em></td>
</tr>
<tr>
<td>3. ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT, or VT induced at electrophysiological study. <em>(Level of Evidence: B).</em></td>
<td>3. ICD implantation is reasonable for patients with hypertrophic cardiomyopathy who have one or more major risk factors for SCD. <em>(Level of Evidence: C).</em></td>
</tr>
<tr>
<td>4. ICD implantation is reasonable for the prevention of SCD in patients with arrhythmogenic right ventricular dysplasia (ARVD)/cardiomyopathy, who have one or more risk factors for SCD. <em>(Level of Evidence: C).</em></td>
<td>4. ICD implantation is reasonable for the prevention of SCD in patients with arrhythmogenic right ventricular dysplasia (ARVD)/cardiomyopathy, who have one or more risk factors for SCD. <em>(Level of Evidence: C).</em></td>
</tr>
</tbody>
</table>
4. ICD therapy is indicated in patients with left ventricular ejection fraction (LVEF) less than or equal to 35%, due to prior myocardial infarction (MI) who are at least 40 days post-MI and are in the New York Heart Association’s (NYHA) functional Class II or III. (Level of Evidence: A).

5. ICD therapy is indicated in patients with nonischemic dilated cardiomyopathy who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. (Level of Evidence: B).

6. ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 35%, and are in NYHA functional Class I. (Level of Evidence: A).

7. ICD therapy is indicated in patients with nonsustained VT due to prior MI, LVEF less than or equal to 35%, and inducible VF or sustained VT at electrophysiological study. (Level of Evidence: B).

5. ICD implantation is reasonable to reduce SCD in patients with long-QT syndrome (LQTS) who are experiencing syncope and/or VT while receiving beta blockers. (Level of Evidence: B).

6. ICD implantation is reasonable for non-hospitalized patients awaiting transplantation. (Level of Evidence: C).

7. ICD implantation is reasonable for patients with Brugada syndrome who have had syncope. (Level of Evidence: C).

8. ICD implantation is reasonable for patients with Brugada syndrome who have documented VT that has not resulted in cardiac arrest. (Level of Evidence: C).

9. ICD implantation is reasonable for patients with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers. (Level of Evidence: C).

10. ICD implantation is reasonable for patients with cardiac sarcoidosis, giant cell myocarditis, or Chagas disease. (Level of Evidence: C).

Searches

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

Searches were conducted on December 22, 2017 using the terms “AED (automated external defibrillator),” “ICD-(implantable cardioverter-defibrillator),” “WCD (wearable cardioverter defibrillator, sudden cardiac arrest (SCA)).”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
Findings

The first clinical evaluations of wearable cardioverter-defibrillators included the Wearable Defibrillator Investigative Trial and Bridge to ICD in Patients at Risk of Arrhythmic Death studies. A total of 289 patients were enrolled; six of eight wearable cardioverter-defibrillator defibrillation attempts were successful; 12 deaths occurred (half of which were patients not wearing the wearable cardioverter-defibrillator); and 23.5 percent discontinued the study from device-related discomfort or adverse reactions (Feldman, 2004).

Early results found wearable cardioverter-defibrillators to be highly accurate in detecting sudden cardiac arrests. Sensitivity in different studies ranged from 90 to 100 percent, with specificity between 98 and 99 percent (Auricchio, 1998; Klein, 2010).

Adherence to treatment protocol presented a concern, as patients wear wearable cardioverter-defibrillators voluntarily, without the presence of health care professionals. In a large study, daily use exceeded 90 percent in more than half of the cohort, and the discontinuation rate was 14 percent (Chung 2010). A study of 2000 patients prescribed wearable cardioverter-defibrillator between August 2011 and February 2014 with ischemic or nonischemic cardiomyopathy, or congenital/inherited heart disease, had a median use of 22.5 hours a day (Kutyifa, 2015).

A Hayes review of 11 studies (n=3516, including 2000 from Kutyifa, 2015), determined findings on safety and effectiveness of wearable cardioverter defibrillator were conflicting, and that more study was needed to better understand the value of the device (Hayes, 2017).

While most wearable cardioverter-defibrillator users are adults, the degree of compliance in children is of particular concern. One study comparing young adults ages 19 – 21 and children under 18 found both groups had an average compliance of 19 hours a day, or 80 percent (Collins, 2010).

A study followed 127 patients with non-ischemic cardiomyopathy who wore a wearable cardioverter-defibrillator for a median of 51 days, 18 hours per day. In the 100 days of follow up, there were nine sustained ventricular events (seven patients), all successfully treated with 100 percent conversion. The authors conclude that wearable cardioverter-defibrillator may be an effective temporary prophylaxis for preventing sudden cardiac death with newly diagnosed non-ischemic cardiomyopathy (Salehi, 2016). Another recent study concludes wearable cardioverter-defibrillator can be safely used to protect patients during period of risk assessment (Kutyifa, 2015).

One common measure of efficacy of wearable cardioverter-defibrillator use is survival. An early study by more than 500 authors examined results from the Home Automatic External Defibrillator trial. A total of 7001 patients with previous anterior wall myocardial infarction who were not candidates for implantable cardioverter defibrillator compared mortality for patients with wearable cardioverter-defibrillator to the standard practices of calling Emergency Medical Services and administering
cardiopulmonary resuscitation. There was no death rate difference in the control and automated external defibrillator groups, 6.5 and 6.4 percent respectively, at a median of 37 months of follow up (Bardy, 2008).

Mortality in a single-center cohort of patients receiving implantable cardioverter defibrillators for traditional indications was similar to the mortality among 3569 wearable cardioverter-defibrillator patients, 4.4 versus 3.6 percent at three months, and 22.1 versus 20.5 percent after three years (Chung, 2010). Compared to 4149 discharged patients with recent revascularization (Coronary Artery Bypass Graft or Percutaneous Coronary Intervention) and a left ventricular ejection fraction <0.35 who did not receive an implantable cardioverter defibrillator at discharge, 809 patients who did receive a wearable cardioverter-defibrillator at discharge had a lower mortality (7 versus 3 percent) after Coronary Artery Bypass Graft, and a lower mortality (2 versus 10 percent) after Percutaneous Coronary Intervention (Zishiri, 2013).

A 2011 study compared one-year survival rates for patients wearing wearable cardioverter-defibrillator by diagnosis. Both groups (119 patients with inherited arrhythmias and 43 patients with congenital structural heart disease) had high survival rates of 97 and 87 percent (Rao, 2011). Of 3569 patients wearing a wearable cardioverter-defibrillator for at least one day in 2002 – 2006, the post-ventricular tachycardia/ventricular fibrillation survival rate was 90 percent, or 72 of 80 (Bloch Thomsen, 2010).

The other often-cited measure of wearable cardioverter-defibrillator efficacy is appropriateness. The above-mentioned study of 3569 patients with 80 sustained ventricular tachycardia/ventricular fibrillation events in 59 patients reported first shock efficacy occurred in 79 of 80 events (Bloch Thomsen, 2010). A report of 8453 patients given wearable cardioverter-defibrillator within 90 days of an MI found 1.6 percent received appropriate shocks (Epstein, 2013). In a study of 809 patients with recent revascularization and left ventricular dysfunction, 1.3 percent had an appropriate shock (Zishiri, 2013).

Another study found equal rates of appropriate and inappropriate shocks of 2.0 percent of wearable cardioverter-defibrillator patients. Causes of inappropriate shocks were mostly due to signal noise and supraventricular tachycardia (Piccini, 2016).

A review of five studies documented rates of adverse events while on a wearable cardioverter-defibrillator, including skin rash/itching (six percent), false alarms (14 percent), and palpitations/light-headedness/fainting (nine percent). It also calculated rates of discontinuation due to comfort/lifestyle issues (16-22 percent), and serious adverse events, including inappropriate shocks (0-2 percent), unsuccessful shocks (0-0.7 percent), and death (0-0.3 percent). Authors concluded that the device was safe, but cautioned that quality of existing evidence in the literature is very low (Ettinger, 2017).

A review of 33 studies (with generally low-quality evidence) concluded that wearable defibrillator use compared with no defibrillator use reduces the chance of ventricular tachycardia/ventricular fibrillation associated deaths by an absolute risk reduction of approximately one percent, achieved by averting approximately 4/5th of all ventricular tachycardia/ventricular fibrillation-associated deaths (Uyei, 2014).
The potential for a temporary wearable cardioverter-defibrillator to become permanent is still under discussion. In one registry of 89 wearable cardioverter-defibrillator patients with idiopathic dilated cardiomyopathy, 42 percent experienced myocardial recovery and did not develop an indication for a permanent implantable cardioverter defibrillator, raising the possibility that wearable cardioverter-defibrillator use can be long-term or even permanent (Kao, 2012).

A study of 140 patients in Philadelphia, 85.9 percent of whom were African-American, used wearable cardioverter defibrillators for a median of 43 days, and wore them for an average of 17.3 hours per day. A total of six shocks occurred in the defibrillators, of which two were appropriate. Only 32 percent of patients received implantable cardioverter defibrillators at completion of using the wearable device. Authors conclude that wearable cardioverter defibrillators were effective in preventing sudden cardiac death, and suggested it may be a cost-effective strategy in patients at risk of such sudden death (Naniwadekar, 2017).

**Policy updates:**

A total of five peer-reviewed references have been added to, and one removed from, this policy in December, 2017.

A total of one professional guideline/other references, and 11 peer-reviewed references have been added to this policy in January 2017.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kutyifa (2015)</td>
<td>Key points:</td>
</tr>
</tbody>
</table>
| Experience of 2000 patients given WCD | • Study of 2000 patients prescribed WCD, August 2011 to February 2014, with ischemic/non-ischemic cardiomyopathy, or congenital heart disease.  
• Median use 22.5 hours/day, median wear time 90 days.  
• 63 ventricular tachyarrhythmias received appropriate WCD shock, 10 inappropriate.  
• At end of WCD use, 42% of patients received ICD. |
| Zishiri (2013)       | Key points:                       |
| Comparison of WCD vs. non-WCD patients after discharge for revascularization | • 809 patients with WCD at discharge vs. 4149 patients with recent revascularization and LVEF <0.35 without ICD or WCD at discharge.  
• Average follow up 3.2 years.  
• WCD group had 3% (90 day) mortality after CABG vs. 7% for non-WCD group.  
• WCD group had 2% (90 day) mortality after PCI, vs. 10% for non-WCD group. |
| Chung (2013)         | Key points:                       |
Role of the wearable cardioverter defibrillator in clinical practice.

- The WCD is an option for external monitoring and defibrillation in patients at risk for SCA caused by VT or VF and who are not candidates for or who refuse an ICD.
- WCDs provide monitoring with backup defibrillation protection. WCDs have been used when a patient's condition delays or prohibits ICD implantation, or as a bridge when an indicated ICD must be explanted.
- WCDs are used for primary prevention of SCD during high-risk gap periods early after MI, coronary revascularization, or new diagnosis of heart failure.

Epstein (2013)

Use of the WCD during mandated waiting periods following MI for patients perceived to be at high risk for SCA

Key points:
- Patients (n=8453) who had a WCD prescribed in the first three months post-MI, with ejection fraction ≤35%, September 2005 – July 2011
- 133 patients (1.6%) received 309 appropriate shocks, of which 91% were resuscitated from a ventricular arrhythmia (median 16 days post-MI)
- 75% treated in the first month, and 96% within the first three months of use.
- Shock success survival= 84 and 95% in non-revascularized, re-vascularized patients.

Chung (2010)

Comparison of patients with WCD vs. ICD

Key points:
- 3569 patients with WCD compared to standard for patients with ICD.
- Three month mortality similar for WCD (3.6%) and non-WCD (4.4%) patients.
- Three year mortality similar for WCD (20.5%) and non-WCD (22.1%) patients.
- First-shock success in 79 of 80 ventricular tachycardia/ventricular fibrillation events for 50 patients; survival in 72 of 80 events.

References

Professional society guidelines/other:


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**


Surveillance of Implantable or Wearable Cardioverter Defibrillators (ICDs): Office, Hospital, Web, or Non-Web Based (L34087) Effective October 1, 2015. CMS Medicare Coverage Database web site. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34087&ver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=wearable+cardioverter+defibrillator&KeyWordLookUp=Title&KeyWordSearchType=And&bc=AAAAACAAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34087&ver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=wearable+cardioverter+defibrillator&KeyWordLookUp=Title&KeyWordSearchType=And&bc=AAAAACAAAAAAA%3d%3d&). Accessed December 22, 2017.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>93745</td>
<td>Initial set-up and programming by a physician of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events</td>
<td></td>
</tr>
<tr>
<td>93292</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>I49.01</td>
<td>Ventricular fibrillation</td>
<td></td>
</tr>
</tbody>
</table>
### HCPCS Level II Code

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>K0606</td>
<td>Automatic external defibrillator, with integrated electrocardiogram analysis, garment type</td>
<td></td>
</tr>
<tr>
<td>K0607</td>
<td>Replacement battery for automated external defibrillator, garment type only, each</td>
<td></td>
</tr>
<tr>
<td>K0608</td>
<td>Replacement garment for use with automated external defibrillator, each</td>
<td></td>
</tr>
<tr>
<td>K0609</td>
<td>Replacement electrodes for use with automated external defibrillator, garment type only, each</td>
<td></td>
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</tbody>
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## Appendix A

AGHRQ – Agency for Healthcare Research and Quality

Guideline Summary – National Guideline Clearinghouse (NGC)-9488

### Guideline title

HRS expert consensus statement on the management of cardiovascular implantable electronic devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy.

### Guideline status:

This is the current release of the guideline.

### Scope

#### Disease/condition(s)

Diseases and conditions, including bradycardia and heart failure, requiring cardiovascular implantable electronic devices (CIEDs)

#### Guideline category

- Counseling.
- Evaluation.
- Management.

#### Clinical specialty

- Cardiology.
- Family Practice.
- Geriatrics.
- Internal Medicine.
- Nursing.
- Pediatrics.
- Psychiatry.
- Psychology.

### Intended Users
• Advanced practice nurses.
• Allied health personnel nurses.
• Patients.
• Physician assistants.
• Physicians.
• Psychologists/non-physician behavioral health clinicians.
• Social workers.
• Other.

**Guideline objective(s)**

• To make clinicians aware of the legal, ethical, and religious principles which underlie withdrawal of life sustaining therapies, including device deactivation, in patients who have made this decision,
• To highlight the importance of proactive communication by the clinician in order to minimize suffering as the end of life nears for patients with cardiovascular implantable electronic devices (CIEDs),
• To provide a management scheme to guide the clinician in assisting a patient with a request to withdraw CIED therapy,

**Target population**

• Adult and pediatric patients with cardiovascular implantable electronic devices (CIEDs) who are nearing end of life or who are considering CIED deactivation for other reasons.
• Family members of the above patients.

**Interventions and practices considered**

• Consideration of ethical and legal principles and precedents.
• Consideration of religious beliefs and principles.
• Communication with patient and family members about the cardiovascular implantable electronic device (CIED) deactivation process.
• Logistics of CIED deactivation, including discussion of alternatives.
• Management of CIEDs in children nearing end of life or requesting withdrawal of treatment.

**Major outcomes considered**

• Mortality rates.
• Rate of painful implantable cardioverter-defibrillators (ICD) shocks.
• Quality of life.
• Patient and family distress.

**Methodology**

**Methods used to collect/select the evidence**

Searches of electronic databases

**Description of methods used to collect/select the evidence**

Medline and PubMed databases were searched. All initial literature searches were performed at the time the document writing committee was initiated in March of 2009. Subsequent literature searches
were performed as needed throughout document development and concluded in May of 2010. Because the document is more of a policy document than a scientifically based research article, no relevant information was excluded. Initial search terms of implantable device and palliative care, communication and ethics were used; each section author was responsible for adding search criteria relevant to their section.

Number of source documents
Not stated

Methods used to assess the quality and strength of the evidence
Not stated

Rating scheme for the strength of the evidence
Not applicable

Methods used to analyze the evidence
Review

Description of the methods used to analyze the evidence
Not stated

Methods used to formulate the recommendations
Expert consensus

Description of methods used to formulate the recommendations
To address this topic, a multidisciplinary writing group was convened consisting of electrophysiologists, patients, and individuals with expertise in the fields of geriatrics, palliative care, psychiatry, pediatrics, nursing, law, ethics, and divinity. Input from industry and patient groups was also solicited and incorporated where relevant. Recommendations are based on consensus of the writing group and confirmed by the Heart Rhythm Society’s established consensus process. Agreement was greater than 90 percent on all recommendations.

Rating scheme for the strength of the recommendations
Not applicable

Cost analysis
A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of guideline validation
Not stated

Description of method of guideline validation
Not applicable

Recommendations

Major Recommendations
Basic Principles

Ethical and legal principles and precedents

- A patient with decision-making capacity has the legal right to refuse or request the withdrawal of any medical treatment or intervention, regardless of whether s/he is terminally ill, and regardless of whether the treatment prolongs life and its withdrawal results in death.
- When a patient lacks capacity, his/her legally-defined surrogate decision-maker has the same right to refuse or request the withdrawal of treatment as the patient would have if the patient had decision-making capacity.
- The law presumes that all adults are competent, defined as the ability to understand the nature and consequences of one’s decisions. Only a court can declare an adult patient incompetent. In most situations, however, clinicians can assess patients’ decision-making capacity and act on these assessments without involvement of the courts.
- Ethically and legally, there are no differences between refusing cardiovascular implantable electronic device (CIED) therapy and requesting withdrawal of CIED therapy.
- Advance directives should be encouraged for all patients with CIEDs.
- Legally, carrying out a request to withdraw life-sustaining treatment is neither physician-assisted suicide nor euthanasia.
- Ethically, CIED deactivation is neither physician-assisted suicide nor euthanasia. When carrying out a patient’s request for withdrawal of a life-sustaining treatment that a patient perceives as unwanted (including CIED therapies), the clinician’s intent is to discontinue the unwanted treatment and allow the patient to die naturally of the underlying disease - not to terminate the patient’s life.
- The right to refuse or request the withdrawal of a treatment is a personal right of the patient and does not depend on the characteristics of the particular treatment involved (i.e., CIEDs). Therefore, no treatment, including CIED therapies, has unique ethical or legal status.
- A clinician cannot be compelled to carry out an ethically- and legally-permissible procedure (i.e., CIED deactivation) that s/he personally views in conflict with his/her personal values. In these circumstances, the clinician cannot abandon the patient but should involve a colleague who is willing to carry out the procedure.

Basic religious principles

- Legal and ethical rationales for respecting patients’ rights to refuse medical treatment are supported by the tenets of major religious traditions in Western culture.
- Depending on the significance (to the patient) of religious belief and its bearing on the decision to be made, it can be part of what motivates a patient to choose or refuse deactivation of CIED devices.
- The distinction between letting life go (allowing to die) and taking life (intending to actively kill) is religiously important, especially for those who appeal to it as part of their religious understanding of justifiable choices regarding death.
- Perception of disproportionate burden caused by continuation of life-sustaining treatment, as determined by the patient, is central to religious justifications of permissibility of letting life go.
- A clinician whose own religious beliefs are not in line with the patient's may not override a patient’s or surrogate's choice. The clinician may, however, appeal to his/her own right not to participate in deactivation—not abandoning the patient but by involving a colleague who
is willing to carry out the procedure.

- Patients should be provided the support they want and need in order to make decisions about deactivation of CIEDs that are coherent with their spiritual and moral beliefs.

**Effectively Putting into Practice the Device Deactivation Process**

**Communication**

- Communication about CIEDs should be a part of a larger conversation about patients’ goals of care. The role of the clinician is to help patients determine how the benefits and burdens of device therapy align with their desired outcomes for their health care.
- Communication about CIED deactivation is an ongoing process that starts prior to implant and continues over time as patient’s health status changes.
- While the role of the clinician is to advise and assist the patient and family, the ultimate decision-making authority rests with the patient; or his/her surrogate, if the patient does not have capacity to make the decision.
- Multiple options are available to the patient, family, and clinicians with regard to the extent of deactivation of CIED therapy and the modalities available, ranging from programming off only certain features such as shock therapy, to discontinuation of all therapy to not replacing a depleting device.

**Logistics of CIED deactivation**

- Any physician or center that implants CIEDs should have a clearly defined process to withdraw therapies at such a time that becomes appropriate.
- Deactivation of CIED therapies requires an order from the responsible physician, preferably written, with appropriate documentation. In emergent situations, a verbal order should be followed by written documentation within 24 hours.
- Documentation prior to deactivation must include the physician's determination that the patient has the capacity to make the decision or that the appropriate surrogate has been identified; that consequences to deactivation have been discussed; and that alternatives have been discussed if relevant.
- A physician order for deactivation must include the specific therapies to be deactivated or re-programmed.
- The deactivation process should include anticipation of symptoms and appropriate palliative care planning tailored to individual patients' needs, as well as the needs of family members when appropriate.
- Deactivation of anti-tachycardia therapies may be achieved by re-programming or by magnet application.
- Deactivation of pacing therapies may be achieved by reprogramming to specific modes or to sub-threshold outputs.
- Any uncertainties about the specifics of deactivation should be clarified by the health care team, ideally in consultation with a physician with electrophysiology expertise.
- The specific resources of acute care facilities, inpatient hospice, long-term care facilities, or patients at home require careful consideration when planning and carrying out a device deactivation.
- All Industry Employed Allied Professionals (IEAP) must work under direct supervision of medical personnel (except in highly rare circumstances).
- Each manufacturer has policies that apply to the deactivation of CIED therapies; it is the
responsibility of the IEAP to ensure that they adhere to these policies.

- Personnel including clinicians and IEAPs who do not wish to personally participate in deactivation should assist in locating qualified individuals who are willing to carry out this request.

Special populations — pediatrics

- Management of CIEDs in children nearing end of life or requesting withdrawal of treatment requires an assessment of the child’s decision-making capacity.
- If a child does not have decision-making capacity, a parent or guardian should make decisions in the child's best interest.
- Even when a child does not have decision-making capacity, communication of decisions should be provided to the child, recognizing their developmental level and individual preferences.

Clinical algorithm(s)
None provided

Type of evidence supporting the recommendations
The type of evidence supporting each recommendation is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential benefits
Improved evaluation, communication, and management (including device deactivation) of patients with cardiovascular implantable electronic devices (CIEDs) nearing end of life

Potential harms
Not stated

Qualifying statements
When using or considering the guidance given in this document, it is important to remember that there are no absolutes with regard to many clinical situations. The ultimate judgment regarding care of a particular patient must be made by the health care provider and the patient in light of all the circumstances presented by that patient.

Implementation of the guideline

Description of implementation strategy
An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

- IOM Care Need.
- End of Life Care.
- Living with Illness.
- IOM Domain.
- Effectiveness.
- Patient-centeredness.
Identifying Information and Availability

Bibliographic source(s)

Adaptation
Not applicable: The guideline was not adapted from another source.

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Financial disclosures/conflicts of interest
See the Appendix in the original guideline document for author relationships with industry.

Guideline endorser(s)
American Academy of Hospice and Palliative Medicine - Professional Association
American College of Cardiology Foundation - Medical Specialty Society
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This is the current release of the guideline.

Guideline availability

Availability of companion documents
The following is available:
- The HRS policy for development and endorsement of clinical guidance documents from HRS and others. Washington (DC): Heart Rhythm Society (HRS); 2009 Sep. 6 p. Available from the Heart Rhythm Society Website.

Patient resources
None available

NGC status
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