American Heart Association | American Stroke Association

September 22, 2011

DME MAC Medical Directors
c/o Paul Hughes, MD
Medical Director
NHIC, Corp.
75 Sgt. William Terry Drive
Hingham, MA 02043

Re: Draft LCD for Automatic External Defibrillators
DL13613, DL27232, DL13877, and DL13577

Dear Drs. Hughes, Brennan, Hoover, and Whitten:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments on the draft local coverage determination for automatic external defibrillators (AEDs).

AHA has serious concerns with the proposal to revise the existing coverage policy for AEDs. Specifically, we are concerned that the revised policy would require Medicare beneficiaries to meet the same requirements for a wearable defibrillator as those that are in place for an implantable cardioverter-defibrillator (ICD). This change would eliminate patients' access to wearable defibrillators in the immediate period after an acute myocardial infarction (MI); a time when they are at high risk for sudden cardiac arrest in addition to other forms of cardiac death.

For the reasons outlined below, we respectfully disagree with the proposed changes and urge you to return to the existing coverage policy for AEDs.

Risk for Sudden Cardiac Arrest and Death

Approximately 300,000 sudden cardiac arrests occur outside of the hospital each year. The most important and treatable cause of sudden cardiac arrest is ventricular tachyarrhythmias such as ventricular tachycardia (VT) or ventricular fibrillation (VF). Immediate treatment, including defibrillation to stop the abnormal heart rhythm, is the only way to restore a normal heart rhythm and the only effective treatment of cardiac arrest caused by potentially lethal ventricular tachyarrhythmias. For every minute that passes without CPR and defibrillation, the chances of survival decrease by 7-10%; and only an estimated 8% of victims who suffer a sudden cardiac arrest outside of the hospital setting survive.[1]

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Sudden cardiac arrest can affect people of all ages, however, the incidence of sudden cardiac arrest increases with advancing age.[2] This is an important factor to consider since this coverage determination applies to the older Medicare population who may be at greater risk for sudden cardiac arrest.

For patients who have suffered an acute MI, the risk for sudden cardiac arrest is particularly high. The VALIANT (Valsartan in Acute Myocardial Infarction) study found that the risk for sudden cardiac death is highest in the first month immediately following a MI, especially in patients with a reduced ejection fraction or heart failure. The risk for sudden cardiac death remains high for the first three months following a MI even if the patient receives optimal medical therapy; moreover, one-fourth of all arrhythmic deaths occur within the first three months after a MI.[3] While the risk for sudden cardiac arrest begins to decline over time, the risk continues to remain elevated when compared to individuals who have never had a MI.[3]

Wearable Defibrillators as Bridge Therapy

To decrease the risk of sudden cardiac arrest and consequent sudden cardiac death post-MI, health care providers may consider surgically implanting an ICD that monitors the heart rate and rhythm and can deliver shocks to correct VT/VF if necessary. ICDs have been shown to reduce mortality from sudden cardiac arrest after a MI. Several trials have found improved survival rates with ICD therapy, particularly in high risk patients who have left ventricular dysfunction due to a prior MI and non-ischemic cardiomyopathy.[2] However, under Medicare, patients are ineligible to receive an ICD in the period immediately following a MI; waiting period requirements must first be met. We understand this restriction; AHA's guidelines recommend that providers wait at least 40 days after a MI before placing an ICD.[2] Yet the risk for sudden cardiac death is highest during the required waiting period.

Fortunately, the existing coverage policy gives providers and patients another option; wearable defibrillators may be prescribed for patients who are at high risk for sudden cardiac arrest after a MI. No waiting period applies.

For patients at high risk after a cardiac event, a wearable defibrillator may be the only option to prevent sudden cardiac death. As noted above, even when patients receive optimal medical therapy, they remain at high risk for sudden cardiac death during the early recovery period following a MI. Thus, other than keeping high risk patients in the hospital for a prolonged time period, which is untenable and costly for providers, patients, and the Medicare program, wearable defibrillators may be the best option for preventing sudden cardiac death in a select patient population.

Consider the BIROAD study, which examined the use of wearable defibrillators as bridge therapy to ICD implantation in post-MI patients. According to the study results, wearable defibrillators are effective in detecting and treating ventricular tachyarrhythmias in patients at high risk for sudden cardiac death. Of 112 study participants who wore a wearable defibrillator for an average of 2.6 months, four successful defibrillations occurred. While two unsuccessful defibrillations were recorded, both occurred in patients who were not wearing the device correctly.[4]

Similar encouraging results were found upon an examination of a nationwide registry of wearable defibrillator patients. Of the 3,569 patient records examined, 80 VT/VF events were recorded in 59 patients. All of the events were converted and patients survived 89.5% of the VT/VF-related events. Among all registry participants, including those with events not related to VT/VF, the overall survival rate was 99.2% with a 0.78% sudden death mortality over an average of 53 days of use. The study's authors note that this survival rate for wearable defibrillators is comparable to that of ICDs.[5]

Because wearable defibrillators are non-invasive and temporary, they also give providers an opportunity to later re-evaluate the patient's condition and determine if the patient's heart muscle has improved. AHA recommends that providers re-evaluate left ventricular function six to eight weeks after an acute MI.[6] Many patients show improvement in heart function at this time point. For example, in the BIROAD study, the most common reason participants stopped using the device was because the study's four-month duration ended or the participants no longer had a qualifying indication for a defibrillator (42%).[4] However, in cases where the heart has not improved sufficiently, providers may then consider ICD implantation. 23% of the participants in the BIROAD study received an ICD by the conclusion of the study.[4]

Wearable defibrillators also present no major complications or risks, other than a low risk of inappropriate shock (0.7%), which is similar to the risk for ICDs (0.6%-1.5%).[5]

These studies demonstrate that wearable defibrillators can be a safe, effective treatment option when an ICD is not appropriate, including the first few weeks or months after a MI or coronary revascularization, after a recent diagnosis of cardiomyopathy, or when it is unclear if there is a need for ICD placement. Wearable defibrillators can protect patients from sudden cardiac death during these high risk time periods and serve as a bridge to an ICD.

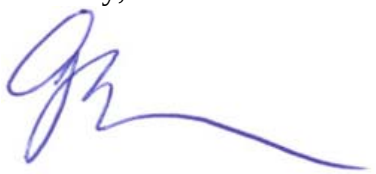
Conclusion

In closing, we reiterate our objection to the proposed revisions to the AED coverage policy. If the revised coverage policy is implemented as proposed, Medicare coverage for wearable defibrillators will be severely restricted and patients will lose access to a valuable treatment option to protect against sudden cardiac death.

Wearable defibrillators are reasonable and necessary for select patients who have experienced a recent MI or other cardiac event that places them at high risk for sudden cardiac arrest. Wearable defibrillators can help these patients *before* they are eligible for an ICD, in situations where ICDs are not indicated, or when it is unclear if implantation of a permanent ICD is necessary. Because wearable defibrillators are intended to fill a void when an ICD is not recommended or allowed, we believe it is inappropriate to create one set of requirements for both wearable defibrillators and ICDs. Instead, we strongly recommend that you return to the existing coverage policy for AEDs.

Thank you for consideration of our comments. If you have any questions or require any additional information, please do not hesitate to contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Sincerely,



Gordon F. Tomaselli, MD, FAHA
President
American Heart Association

[1] American Heart Association. Heart Disease and Stroke Statistics 2011 Update. Circulation.
[2] ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. Circulation: 2006.
[3] Leonard Ganz, et al. Role of Implantable Cardioverter-Defibrillators for the Primary Prevention of Sudden Cardiac Death After Myocardial Infarction. UpToDate.com.
[4] Arthur Feldman, et al. Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death: Results of WEARIT/BIROAD. PACE: January 2004.
[5] Mina Chung, et al. Aggregate National Experience with the Wearable Cardioverter-Defibrillator: Event Rates, Compliance, and Survival. J. Am. Coll. Cardiology: July 2010.
[6] T. Jared Bunch, et al. Mechanisms of Sudden Cardiac Death in Myocardial Infarction Survivors: Insights from the Randomized Trials of Implantable Cardioverter-Defibrillators. Circulation: 2007.