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Heart Beat

Some defibrillator stats:

■ **1.3 million**

Americans are eligible for defibrillators based on current criteria

■ **160,000**

defibrillators were implanted in 2005

■ Cost of a defibrillator: about **\$35,000**

■ Cost of a Cambridge Heart test: about **\$400**

Sources: University of Michigan Health System; St. Jude Medical

Medicare Says It Will Cover Test For Heart Device

By SYLVIA PAGÁN WESTPHAL
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A little-known test that predicts which patients make the best candidates for implantable heart defibrillators has received the nod for federal insurance coverage, a move that could damp the outlook for the hot-selling devices.

The noninvasive cardiac test, developed by Bedford, Mass., Cambridge Heart Inc., uses a machine to measure nearly undetectable fluctuations in a person's heartbeat during mild exercise.

Yesterday the federal Centers for Medicare and Medicaid Services, or CMS, decided to allow Medicare reimbursement for the \$400 test on a national level, boosting prospects for Cambridge Heart, which has been struggling, and bringing some level of closure to a contentious debate about the test's merits. Medicare is the federal-state insurance program for the elderly. Yesterday's decision doesn't extend to Medicaid, the parallel program for the impoverished.

The test detects fluctuations associated with higher risk of life-threatening problems with heart rhythm. If the test is positive, the patient is considered to be at risk for sudden cardiac death, making a defibrillator highly recommended. If the test is negative, there is a low chance -- only about 3% -- that the patient will die of a life-threatening heart rhythm episode within two years, making the need for a defibrillator less clear.

Cardiac defibrillators send an electric jolt to a heart that has stopped working because of abnormal beating. Manufacturers have painted a robust sales outlook, saying the devices are being implanted each year in only about 10% to 15% of the people who need them. **Boston Scientific Corp.** agreed to buy **Guidant Corp.** for about \$27 billion in large part to get in on the defibrillator boom. **Medtronic Inc.** and **St. Jude Medical Inc.** are leading makers of the devices. World-wide sales of defibrillators totaled some \$5.5 billion last year, up about 19% from 2004.

Based on fairly new criteria established last year by the Medicare agency, manufacturers estimate that about 1.3 million Americans are considered candidates for a defibrillator. The Medicare criteria, mirrored by most big private insurers, are based on how well a person's heart functions. They came about after two large studies showed that among patients who didn't have obvious heart-rhythm problems but who did exhibit certain other characteristics -- such as low heart performance and evidence of heart failure -- implanted defibrillators saved lives.

But studies of the Cambridge Heart test have shown that 30% of those patients don't have the telltale abnormal heartbeat that suggests a risk of sudden cardiac death, and therefore are less likely to need a defibrillator. If the test were widely used to make decisions about whether to implant defibrillators, it would cut about 465,000 patients out of the pool of eligible people, according to Bruce Nudell, an analyst with Bernstein Research.

Mr. Nudell says a depletion of the eligible patient pool is "somewhat concerning" for device manufacturers in the long run. However, in the near term, Mr. Nudell says the Cambridge Heart test could boost the number of defibrillators implanted, if it helps some doctors overcome resistance. Doctors and patients are sometimes reluctant to implant defibrillators because of concerns over expense, surgical risks of implantation, and the uncertainties involved in determining who is a candidate.

Paul Chan, a cardiology fellow at the University of Michigan, Ann Arbor, who has studied the Cambridge Heart machine and its cost effectiveness, says Medicare could potentially save about \$700 million a year if doctors implanted defibrillators only in patients who test abnormally. "Not only is it a more cost-effective approach, it's a more sustainable approach," says Dr. Chan, whose work hasn't been funded by Cambridge Heart.



In its coverage decision yesterday, CMS didn't go so far as to make the test a prerequisite for coverage of implantation. Defibrillator manufacturers -- many of which are doing their own clinical trials of the Cambridge Heart test -- oppose such a requirement. Medical societies including the

Heart Rhythm Society and the American College of Cardiology also have argued against such an insurance requirement. The medical groups cite evidence from previous clinical studies suggesting the Cambridge Heart test is a helpful tool but not so conclusive that it should be the sole basis for defibrillator decisions.

In a January letter to Medicare, officials from Guidant, the second-largest

manufacturer of defibrillators, said the company was "especially concerned for the long-term well-being of patients who test negative" and go on to suffer a life-threatening heart rhythm problem in the future.

Michael Mirro, medical director of the Clinical Research Center at Parkview Hospital in Fort Wayne, Ind., and a spokesman for the cardiologists group, said the Medicare decision "puts the tool in the hands of the physicians." Some patients don't perfectly fit the criteria for a defibrillator, but a doctor could be concerned about them anyway, he says. The Cambridge Heart test could come in handy in those situations, allowing the doctor to have peace of mind if the patient tests negative but prompting the doctor to do more tests if it comes out positive.

National Medicare coverage of the test, which is already reimbursed by Medicare in some states, is expected both to expand the pool of patients who might use the test and to trigger more coverage on the part of private insurers, who often take cues from Medicare when making their own coverage decisions. Right now, only about 10% of private insurance companies cover the test.

The decision is expected to be a boon for Cambridge Heart, whose 2005 revenue of \$4.2 million represented an almost 18% decline from the year before. David Chazanovitz, chief executive of Cambridge Heart, says the Medicare decision validates "what we've worked on for over a decade." He played down the notion that his test could hurt the defibrillator market, stating that in the near term the test would probably help more doctors get the devices to people who need them. Cambridge Heart's shares are up over 300% since the start of 2006 -- trading at \$2.92 on the OTC Bulletin Board, but down 52 cents, or 15%, yesterday -- on expectations the test would get Medicare coverage.