

ArrhythmiaNEWS

From the Arrhythmia Service of St. Luke's-Roosevelt Hospital Center

Arrhythmia News is a physician bulletin providing arrhythmia updates and information on services at **St. Luke's-Roosevelt Hospital Center** which may benefit your practice and your patients.

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Medicare Expands Indications for Implantable Defibrillators

In June 2003, Medicare formalized the clinical indications that determine reimbursement for implantable cardioverter defibrillators for its covered patients. Although these indications encompass many of the traditional ones, specific restrictions were also implemented. Most notably, the population of patients who were previously shown to benefit from ICD in the **MADIT II** study (prior MI, EF < 30%) were restricted to the approximately one third of patients with QRS duration >120 ms. In addition, patients with non-ischemic cardiomyopathy were not covered.

As you know, this decision engendered a great deal of controversy and subjected potential ICD recipients to a cumbersome process of screening that included important criteria related to insurance coverage. **The Centers for Medicare and Medicaid Services** (CMS) were lobbied to alter this restrictive process but a decision was deferred until additional clinical trial data were available.

Several months ago, the **Sudden Cardiac Death Heart Failure Trial** (SCD-HFT) results were presented at the American College of Cardiology. This newsletter previously highlighted the findings in the study. In summary, the study enrolled patients with ischemic and non-ischemic cardiomyopathy, mild to moderate congestive heart failure, and an ejection fraction < 35%. These patients were shown to benefit from the ICD, with a reduction in overall mortality of 23%. These results were submitted to CMS in an effort to encourage a change in the formal covered indications.

Clinical Indications Added

In late September 2004, CMS issued a "Draft Decision Memo" that indicated that there was now evidence to conclude that the ICD indications should be expanded and notably will include the following two groups:

- Patients with ischemic dilated cardiomyopathy, documented prior myocardial infarction, and LVEF < 30%.
- Patients with non-ischemic dilated cardiomyopathy greater than nine months and LVEF < 30%.

In addition, previous indications were continued including documented cardiac arrest, sustained ventricular tachyarrhythmia (spontaneous or at EP study), familial or inherited conditions with high risk of sudden death (long-QT syndrome, hyper-

trophic cardiomyopathy), and **MADIT I** (prior MI, EF < 35%, inducible sustained VT at EPS).

These new guidelines also formalized that patients must not have NYHA Class IV heart failure, cardiogenic shock, CABG or PCI within three months, acute MI within one month, need for coronary revascularization, or any disease associated with shortened survival less than one year.

Registry to Be Established

Further, CMS took the unusual step that the "use of ICDs for primary prevention of sudden cardiac death is reasonable and necessary" "only if the beneficiary receiving the ICD implantation is enrolled in either an FDA-approved category B IDE clinical trial or a qualifying national data base (registry)." CMS went on to describe that this registry is needed to ensure that hospitals and providers are certified as competent for ICD implantation, that hospitals and providers report data on all patients undergoing ICD implantation, and that collected data includes patient and device characteristics, details about the facility and provider, and nature of underlying heart disease.

In addition, prospective data will be required including ICD device events for VT/VF and patient outcomes. CMS required that specific hypotheses be addressed. This data collection process will be organized by

providers, industry and physicians, in consultation with reputable scientific agencies.

The decision document has a 60-day comment period after which it may become official policy. We are hopeful that these expanded indications will be implemented around **January 1, 2005**.

It is however uncertain how the "National ICD Registry" will be established, implemented and funded. CMS is attempting to determine if it is possible to develop more refined clinical criteria that select patients who would most likely benefit from ICD, and exclude patients who do not require ICD or face increased risk or no benefit. This is a substantial undertaking.

Devices in Clinical Trials

CMS re-emphasized that other clinical indications are not currently covered by Medicare and could only be implanted as part of a Category B IDE trial.

Interestingly, CMS indicated that single lead shock-only devices should be used for primary prevention. If

more sophisticated or dual chamber device is selected, appropriate documentation must be available to verify the medical necessity for these more advanced (i.e. expensive) ICDs. The clinical justification must be based on established literature.

Overall this is very good news and we should now be able to expand the use of the ICD to those patients determined to benefit from well-designed large multicenter randomized clinical trials. The timetable is still a bit fuzzy and the practical and administrative implementation will be more difficult than usual, but we are hopeful that our patients can receive ICDs as clinically appropriate.

These new regulations will also put a premium on correct interpretation and application of official guidelines, including types of devices, participation in scientific registries, and EP certification. Financial penalties are likely to result from departure from these regulations.

Please refer appropriate ICD candidates to our offices and physicians for evaluation and consultation given these new Medicare indications. If

you have any questions, do not hesitate to call.

Reference

www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=139

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