

December 16, 2005

Medicare Coverage of Implantable Cardiac Defibrillators (ICD) for Primary Prevention

AT A GLANCE

The Issue:

The Centers for Medicare & Medicaid Services (CMS) requires that hospitals submit patient data when implanting automatic implantable cardiac defibrillators (ICDs) in Medicare patients for primary prevention of sudden cardiac arrest. If the data is not provided to the ICD registry, then CMS will recoup payments from those hospitals that do not submit information. While this coverage policy has been in place since Jan. 27, 2005, CMS recently contracted with the American College of Cardiology – National Cardiovascular Data Registry (ACC-NCDR) to provide the patient registry tool. All hospitals that are implanting ICDs for primary prevention need to contact the ACC-NCDR by Jan. 1, 2006 to register and begin reporting to the ACC-NCDR ICD Registry™.

What You Can Do:

- Share this advisory with your chief financial officer, quality outcomes reporting staff, cardiology department, and cardiologists on your medical staff.
- Go to the ACC-NCDR at https://www.accncdr.com/webncdr/ICD/Default_ssl.aspx by Jan. 1, 2006 and register your intent online to participate in the ACC-NCDR ICD Registry™.
- Educate and train cardiologists and cardiology department staff on the requirement to collect and report the appropriate information for the ACC-NCDR ICD Registry™.
- Ensure that your hospital is reporting patient information in the ICD registry for patients receiving ICDs for primary prevention.

Further Questions:

Contact Nancy Foster, AHA vice president for quality & patient safety, at (202) 626-2337 or nfoster@aha.org or Don May, AHA vice president for policy, at (202) 626-2356 or dmay@aha.org.

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BACKGROUND

In 1986, Medicare began covering automatic implantable cardiac defibrillators (ICDs), and has expanded its policies for this device over the years. In January, the Centers for Medicare & Medicaid Services (CMS) announced it would further expand Medicare coverage of ICDs for primary prevention, based on results of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) sponsored by the National Institute of Health's National Heart, Lung and Blood Institute. This decision increased the number of Medicare beneficiaries eligible for an ICD by one-third to nearly 500,000. But the coverage expansion also included a requirement for hospitals to submit data to an ICD registry as a criterion for coverage and payment.

CMS will use registry data to answer clinical questions posed in its January 2005 decision memorandum, such as whether the indications for ICD implantation in the Medicare population are similar to the patients who received ICDs in the SCD-HeFT and other trials. This effort is part of CMS' new Coverage with Evidence Development initiative, which expands access to important new treatments while facilitating the collection of evidence so that CMS can continue to monitor the effects of its coverage decisions.

Since the decision, CMS has been gathering ICD data using its Quality Network Exchange (QNet) platform, which the agency also uses to collect other health care quality data, including data for the Hospital Quality Alliance. Unfortunately, CMS did not effectively notify hospitals about enrolling in the QNet ICD registry. As a result, compliance and reporting have been problematic. Many hospitals that have been implanting ICDs since Jan. 27, 2005 have not been submitting information to the registry. **But, it's critical to note that hospitals are required to submit information for all Medicare patients who, since Jan. 27, 2005, received ICDs for primary prevention.**

CMS will require hospitals to transition their current ICD data reporting activities from its QNet ICD Abstract Tool to the American College of Cardiology – National Cardiovascular Data Registry’s (ACC-NCDR) ICD Registry™. This transition must be completed by April 1, 2006.

AT ISSUE

Reporting Tools

Hospitals currently can use one of three methods to report ICD data. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the Food and Drug Administration, in the QNet ICD Abstraction Tool, or the new ACC-NCDR ICD Registry™. The QNet registry is temporarily available to all hospitals through the same network they use to submit quality measures for the Hospital Quality Alliance. Each hospital’s QNet administrator has access to this system. Information regarding technical use of the QNet registry in addition to the software for the abstraction tool is available on the QNet Web site at www.qnetexchange.org. **However, CMS has begun the transition to the ACC-NCDR ICD Registry™ and hospitals will not be able to use the QNet ICD Abstraction Tool after April 30, 2006.** CMS encourages hospitals to transition to the new registry as soon as possible. For hospitals that have not submitted any ICD registry data, CMS encourages them to use the new ACC-NCDR ICD Registry™ in order to avoid learning both tools.

Use of the initial QNet Abstraction Tool was intended to be a temporary measure, and moving to the ACC-NCDR ICD Registry™ will allow hospitals to receive benchmarking and quality reports to help improve cardiac patient care. Participation in the ACC-NCDR ICD Registry™ is free for the basic reporting requirement; however, the NCDR offers special reports and services to participating hospitals for a fee.

Data Elements

The ICD Registry™ data elements and definitions represent a comprehensive data set that fulfills the goal of meeting the CMS ICD coverage decision and the research elements needed for CMS to continue to study the appropriateness of Medicare’s ICD coverage policies.

The initial registry was a one-page set of demographic and clinical questions. However, the ACC-NCDR Registry™ has been expanded to three pages and incorporates more patient characteristics and outcomes information. A copy of the ACC-NCDR ICD Registry™ is attached and also available at www.accncdr.com/WebNCDR/ICD/ELEMENTS.ASPX.

While the QNet ICD Abstraction Tool collected information only for Medicare patients, the ACC-NCDR registry is able to collect information for all patients receiving ICDs, both for historical uses and primary prevention.

Important Dates and To Do's

CMS' coverage decision began Jan. 27, 2005. Hospitals should continue to enter data into the QNet ICD Abstraction Tool until they have registered with ACC-NCDR and have transitioned to its ICD Registry™. Hospitals are not required to enter data into both registries at the same time. However, because CMS will no longer accept data from QNet as of April 30, 2006, hospitals are encouraged to begin their transition away from the QNet tool as early as possible, but no later than April 1, 2006.

Hospitals must contact the ACC-NCDR directly and begin the application process by completing the easy web-based “Intent to Join” form no later than Jan. 1, 2006 in order to ensure that they can complete enrollment before April 1, 2006. Additional information about participation is available on the ACC-NCDR Web site at www.accncdr.com/webncdr/ICD, or by telephone at (800) 253-4636, ext. 451.