

QRS Interval Dropped

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meet all CMS coverage requirements for a cardiac resynchronization therapy device, according to the decision memo.

This expanded coverage is more generous than those issued in a draft decision issued in September, which proposed excluding patients with an LVEF of at least 30% or NYHA class IV disease.

Cardiologists who implant ICDs are pleased with the decision. "When you look at the difference between the proposed rule and the final rule, [CMS]

clearly listened to the medical profession and took our advice" along with considering the evidence from clinical trials, said Dr. Stephen C. Hammill, president of the Heart Rhythm Society.

The ICD coverage determination came exactly a week after publication of the results from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) on Jan. 20 (N. Engl. J. Med. 2005;352:225-37). The timing was no accident, since CMS is required to base its decisions on evidence that has been published in

peer-reviewed medical journals.

The SCD-HeFT trial, which involved more than 2,500 patients, looked at whether ICDs improved survival compared with amiodarone or placebo in patients with NYHA class II and class III heart failure and a left ventricular ejection fraction less than 35%. The trial included patients with nonischemic as well as ischemic dilated cardiomyopathy. Researchers found that patients with ICDs had 23% lower mortality than did the placebo group, a statistically significant result.

The CMS decision also addressed the issue of a patient registry. In its September coverage proposal, CMS required that pa-

tients receiving ICDs be placed in a yet-to-be-developed patient registry so that researchers could track outcomes and best practices. But the Heart Rhythm Society and other specialty groups complained that it would be impossible to set the registry up by Jan. 1, as CMS wanted (CARDIOLOGY NEWS, December 2004, p. 1).

Instead, CMS will cover the device in patients who are registered in an already existing registry called Quality Network Exchange, or QNet, which is maintained by the Iowa Foundation for Medical Care.

"The QNet will be the first part of the registry until a more sophisticated registry ... is put

together and goes into place sometime in the next 6 months," said Dr. Hammill, who is among those charged with setting up the new registry.

Dr. Hammill, who is director of heart rhythm services at the Mayo Clinic, Rochester, Minn., estimated that 500,000 patients will be candidates for ICD coverage under the new criteria. "But we know that in the past, with other indications for defibrillators, only about 20% of the patients who are candidates actually get the device," which costs between \$30,000 and \$40,000, he said. Each year, 65,000-70,000 new patients will become candidates, he added. ■

CMS Poised to Cover Carotid Stents in Patients Outside of Clinical Trials

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

In December, Centers for Medicare and Medicaid Services issued a draft decision memo that advises expanding coverage of carotid artery stenting.

Currently, the implantation of carotid stents is covered only in the context of a clinical trial, but under the proposed criteria, stents would be covered in patients who would be high-risk candidates for endarterectomy and who have symptomatic carotid artery stenosis of at least 70%.

The draft decision memo also addresses the qualifications for the providers installing the stent, noting that stenting should be performed "in facilities and by physicians who have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We propose that competency will be determined through a national evalua-

tion process by a recognized entity using approved standards."

The Society for Cardiovascular Angiography and Interventions (SCAI) expressed appreciation for CMS's work on the guidelines. "I think CMS did a thoughtful job in making its decision," said Joseph Babb, M.D., past president of SCAI and chair of its advocacy committee. "But the society is also concerned that there were certain areas that did not seem to get adequate attention."

In a letter sent to the agency, SCAI noted: "The decision severely limits patient access to carotid stenting in asymptomatic high surgical risk patients in need of carotid revascularization, thereby relegating them to one of two potential therapeutic courses: medical or surgical.

"While we are strong supporters of aggressive medical therapy for all patients with or at risk of atherosclerotic disease, it remains unproven as to its effectiveness in high surgical-risk patients, and therefore should not be designated as a default

strategy," the letter continued.

Surgical revascularization, on the other hand, "has been demonstrated to result in statistically similar outcomes as stenting, [but] there are strong trends suggesting it is an inferior approach in most high risk patients," the letter continued. "The continued access to surgery, but not to stenting, for these patients is a fundamental flaw with the draft decision and a break in logic difficult to understand or explain to those in our care."

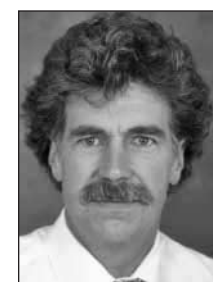
The carotid stent proposal comes on the heels of a series of "firsts" for the device. For example, on Sept. 7, 2004, only a week after the Guidant RX ACCULINK carotid artery stenting system was approved by the Food and Drug Administration, CMS announced that it would cover the device in certain clinical trial participants, but that stent implantation had to be performed by qualified providers who had undergone a multistep training program (CARDIOLOGY NEWS, October 2004, p. 1). ■

Editorial Advisory Board Additions

CARDIOLOGY NEWS is pleased to welcome five new members to its Editorial Advisory Board:



Prakash C. Deedwania, M.D., is professor of medicine at the University of California, San Francisco, and chief of the cardiology section at the Veterans Affairs Medical Center/UCSF Program in Fresno.



James J. Ferguson III, M.D., is associate director of cardiology research at the Texas Heart Institute and codirector of the Cardiology Fellowship Training Program, St. Luke's Episcopal Hospital, Baylor College of Medicine, Houston.



Natesa G. Pandian, M.D., is director of the cardiovascular imaging and hemodynamic laboratory at the Tufts-New England Medical Center, Boston, and associate professor of medicine and radiology at Tufts University.



Neil J. Stone, M.D., is professor of clinical medicine (cardiology) at the Feinberg School of Medicine of Northwestern University, Chicago, and a practicing internist-cardiologist-lipidologist at Northwestern Memorial Hospital.



Paul D. Thompson, M.D., is director of preventive cardiology at Hartford Hospital and professor of medicine at the University of Connecticut, Farmington.

Aortic Aneurysm Graft Recommended for Approval

GAITHERSBURG, MD. — The Food and Drug Administration's Circulatory System Devices Panel voted 8 to 2 to recommend approval, with conditions, of a thoracic endovascular graft for the treatment of thoracic aortic aneurysms.

The Gore TAG Thoracic Endoprosthesis device offers a less invasive, endovascular solution to surgery for thoracic aortic aneurysms (TAAs), according to the manufacturer, W.L. Gore and Associates. The stent-graft device is delivered via a fluoroscopy-guided balloon catheter to the aorta, where it is expanded to seal off the aneurysm and relines the artery wall. The graft is made of expanded polytetrafluoroethylene, fluorinated ethylene propylene, nitinol wire, and gold.

Andrew Farb, M.D., a member of the FDA panel's review team, presented a confirmatory study of the modified device that compared 51 Gore TAG patients (median age 71 years, 65% male) with 94 surgical control patients (median age 68 years, 51% male). In this nonblinded, nonrandomized, prospective, single-arm study, aneurysm diameters in the TAG and control groups were similar, at about 63 mm. At 30 days, at least one major adverse event occurred in 12%

of TAG patients, compared with 70% of the surgical patients. None of the TAG patients died during the first 30 days, compared with 6% of the surgical patients. No ruptures were reported in TAG patients.

The mean length of ICU stay was significantly shorter in the TAG group than the surgical group, as was the mean length of hospital stay. The TAG group experienced less median blood loss than the controls and returned to normal daily activities sooner.

The device won recommendation for approval with numerous conditions, including initiation of a large postmarketing study, and a 5-year follow-up study for patients in the confirmatory study group. The company recommended that training in use of the device target endovascular surgeons, but the panel didn't list this as a condition.

If the FDA follows the recommendation, the Gore TAG will be the first thoracic endovascular graft approved for use in the United States. The agency usually follows the advice of its advisory panels, although it is not bound to do so.

—Deeanna Franklin