SCD-HeFT Results Swayed CMS

ICD, *from page 1*

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

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

"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 Stephen C. Hammill, M.D., president of the Heart Rhythm Society.

The ICD coverage decision came 1 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). CMS is required to base its decisions on evidence 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 patients 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 (INTERNAL MEDICINE NEWS, Dec. 1, 2004, p. 4).

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 Expand Carotid Stent Coverage

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

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

The draft also addresses the competency requirements, 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. … Competency will be determined through a national evaluation 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. "CMS did a thoughtful job in making its decision," said Joseph Babb, M.D., SCAI past president 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 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."

—Joyce Frieden