Societies Rate Cardiac Device Use

The explosive growth of electronic implantable cardiac devices has spurred the release of criteria to guide their use -- and, hopefully, their reimbursement.

The new Appropriate Use Criteria -- developed by the American College of Cardiology, the Heart Rhythm Society, and other key specialty groups, including the American Heart Association -- take a bold step, marking several indications as appropriate even though they are not reimbursed by Medicare, Andrea M. Russo, MD, co-chair of the writing committee, told *MedPage Today*.

A lot of evidence for the use of implantable cardioverter defibrillators (ICDs) has emerged over the last decade, but payment decisions by the Centers for Medicare and Medicaid Services (CMS) have not kept pace. The agency last issued a national coverage decision for ICDs in 1995.

For example, Medicare won't reimburse for an ICD implanted within 90 days of revascularization -- either percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) -- for patients who have had a prior heart attack or who have preexisting cardiomyopathy.

"Yet there is no evidence showing that implanting an ICD in these scenarios is not a good thing to do," said Russo, director of electrophysiology and arrhythmia services at Cooper University Hospital in Camden, N.J.

Consequently, the writing committee has given two thumbs up (appropriate use score 7-9) for these indications:

- Indication 91 -- Left ventricular ejection fraction (LVEF) ≤30% due to old infarction, (40 days or less) NYHA class I (appropriate use score 8)
- Indication 93 -- LVEF ≤35% due to nonischemic causes,(more than 3 months) NYHA II-III (appropriate use score 8)

The committee also deemed it appropriate to implant an ICD in patients who have recently undergone valve surgery that included incidental CABG (same hospitalization or within 3 months), the LVEF is ≤35%, and there are signs the patient needs a pacemaker (indication 113, appropriate use score 7).

"These are just a few of the indications where gaps exist between the evidence and the reimbursement," Russo said. "One of the problems is we don't have a mechanism to address these gaps on a regular basis. We can't just go to the local payer and negotiate for payment."

Department of Justice Sparks Fear

Electrophysiologists have also been a bit leery about implanting ICDs ever since the Department of Justice launched an investigation of ICD prescribing [1] in late January 2011. The agency said too many devices were being implanted without a justification based on published guidelines [2].

After studying the matter, the DOJ published a document, known as the Resolution Model, in August 2012 that defines which so-called inappropriate implant scenarios may result in department action seeking payment of damages.

Russo said that many of the so-called inappropriate scenarios the DOJ will *not* pursue for damages, align with the new Appropriate Use Criteria.

Indication 113 above, for example, was also cited by the DOJ as appropriate: "Patient qualifies for permanent pacemaker (PPM) and (other than the waiting periods) also qualifies for an ICD."

"Implanting a pacemaker only to replace it with an ICD after the 90-day waiting period puts the patient at great risk and is more costly for the healthcare system," Russo said.

The Resolution Model is at least a temporary mechanism by which physicians can be reimbursed until CMS reviews current evidence and changes its coverage decision, Russo said. "But we still need a process that allows for faster review on a regular basis."

New Words Clear Things Up

The new Appropriate Use Criteria address six areas: ICDs for secondary prevention, ICDs for primary prevention, comorbidities, cardiac resynchronization therapy (CRT) devices, generator replacement, and dual- versus single-chamber ICDs.

The document contains 369 real-life clinical scenarios that are intended to help guide physician decision-making decisions, but "should not be considered substitutes for sound clinical judgment and practice experience."

For the first time in the appropriate use arena, the terminology that applies to whether an indication is appropriate or not has been changed, Russo noted.

The typical designations are appropriate, uncertain, or inappropriate. The new terms are:

- Appropriate care
- May be appropriate care
- Rarely appropriate care

Many people were confused by the term "uncertain" and thought the term "inappropriate" meant that a procedure could never be done under any circumstances, Russo said.

"There may not be overwhelming evidence to suggest a particular procedure can be recommended in every situation, but it may be appropriate for individual cases," she said.

Finally, the HRS is involved in creating an app so the 369 scenarios will be readily accessible and easier to navigate, Russo said.

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