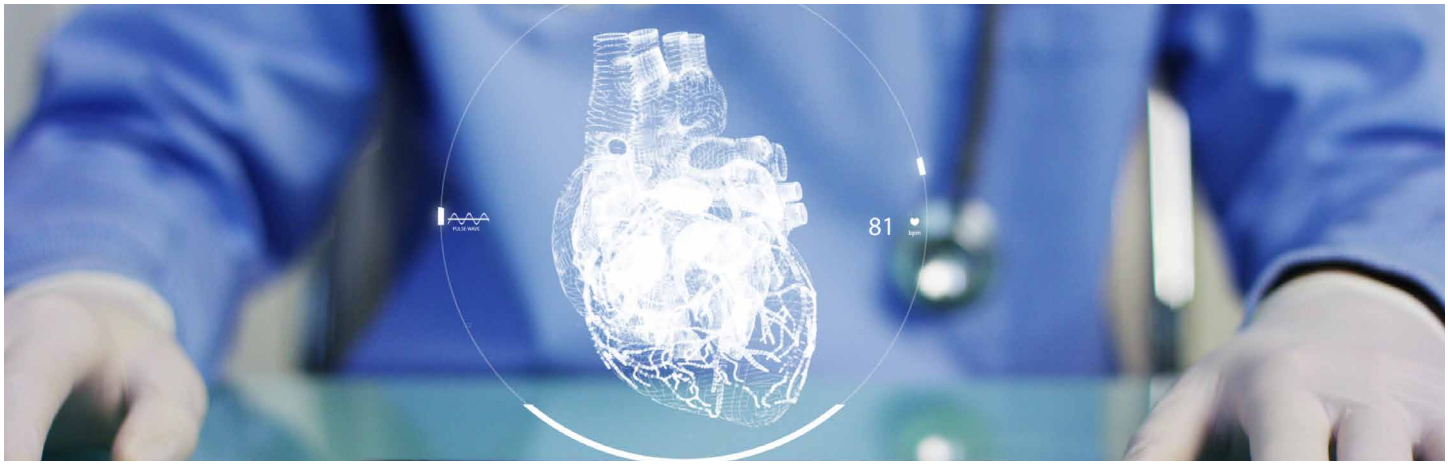

Meeting New Medicare Requirements for Implantable Cardioverter Defibrillators

By Joanna Malcolm on April 23, 2018

POSTED IN HEALTHCARE REFORM, MEDICARE, SOCIAL SECURITY / MEDICARE, TECHNOLOGY, UNCATEGORIZED

On February 15, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a Decision Memorandum revising the National Coverage Determination (NCD) 20.4 on implantable cardioverter defibrillators (ICDs). This is the first update to NCD 20.4 since its implementation in 2005. (As of April 13, 2018, NCD 20.4 has not been updated online and there is no implementation date.)

Specifically, the Decision Memorandum revises patient criteria, exceptions to waiting periods, and registry requirements for NCD 20.4. These changes significantly impact the billing and documentation required by hospitals and physicians to demonstrate medical necessity and thus receive Medicare reimbursement for ICD implantation.

Most significantly, CMS now requires, in most cases, a "formal shared decision making (SDM) encounter [between the patient and provider] . . . using an evidence-based decision tool on ICDs prior to initial ICD implantation." According to CMS, the purpose of these encounters is to provide patients with more information on other treatment options and potential outcomes, thus empowering patients to make the best decisions for their specific conditions.

In its Decision Memorandum, CMS stresses that this requirement is not currently provided through informed consent documentation, which only covers the risks and benefits of the specific procedure. While CMS does not require a specific tool be used for the SDM encounter, the agency has provided an example of an appropriate SDM tool. Access the tool here.

Other NCD 20.4 provisions include the following:

- Making changes to the waiting periods for new and replacement ICDs.
- Adding the use of cardiac MRI testing to the list of modalities that may be used to evaluate left ventricular ejection fraction (LVEF).
- Clarifying medical necessity support documentation for ICD implantation, stating the "clinicians must have tried for at least three months to optimize medical therapy to the extent tolerated by the patient" for non-ischemic cardiomyopathy with heart failure population. If the patient is unable to tolerate "optimal medical therapy" and the outcomes are documented in the patient's medical record, then the requirement has been fulfilled.

- Eliminating the requirement of Class IV heart failure for cardiac resynchronization therapy (CRT) (and noting no other changes impact CRT).

NCD 20.4 is one of the most specific coverage documents provided by CMS, and experience has shown ICDs are a frequent target of CMS audit and recovery efforts. To withstand such scrutiny, the medical record must contain specific documentation to support medical necessity and include specific diagnoses, timeframes, and measurements. For more in-depth information and guidance on NCD 20.4 and other CMS billing requirements, contact Lori Foley, Denise Hall-Gaulin, or Joanna Malcolm at PYA (800) 270-9629.