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CMS ISSUES IMPORTANT DECISION MEMO ADDRESSING UPDATES TO NATIONAL COVERAGE DETERMINATION FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

On February 15, 2018, the Centers for Medicare & Medicaid Services ("CMS") released a long-awaited Final Decision Memo (the "Memo") updating the National Coverage Determination for implantable automatic defibrillators (NCD 20.4), also known as Implantable Cardioverter Defibrillators ("ICDs"). CMS's update to NCD 20.4, the guidance describing when providers may bill and receive payment from CMS for ICDs, comes more than two years after the Department of Justice ("DOJ") concluded its national investigation of ICD billing and False Claims Act settlements with nearly 500 hospitals in 43 states with total recoveries exceeding $250 million. DOJ alleged that hospitals implanted ICDs in Medicare beneficiaries in violation of Medicare coverage requirements outlined in NCD 20.4, specifically the 40-day waiting period following a myocardial infarction ("MI") and 90-day waiting period following a coronary artery bypass graft ("CABG") or percutaneous transluminal coronary angioplasty ("PTCA"). During the course of the investigation, hospitals and providers expressed concerns that NCD 20.4, issued in January 2005, no longer reflected the current state of medical science and evidence-based cardiac medicine. As a result, we understand CMS received numerous request from the medical community to update the NCD. Regardless of whether CMS was responding to concerns raised during the DOJ investigation, what is important is that NCD 20.4 was opened for reconsideration leading to the changes addressed in the Memo.

Although CMS characterized its revisions to NCD 20.4 as "relatively minimal changes," the revisions to the prior version of NCD 20.4 touch upon a number of different coverage indications. These changes include, but are not limited to, the creation of two exceptions to the waiting period requirements, changes to certain patient-related covered indications criteria, a new requirement of patient shared decision-making and use of an evidence-based decision tool, and termination of the registry data collection requirement. The full Memo from CMS may be found here.

BACKGROUND

Since first providing Medicare coverage for ICDs to treat life-threatening ventricular tachyarrhythmias in 1986, CMS expanded coverage of ICDs in 1999 and 2003 to include additional types of cardiac patients and cardiac health conditions. CMS made other changes to the procedure codes and made maintenance updates over the years. However, the most noteworthy modifications were made in 2005 when CMS updated NCD 20.4 to translate it into a formal policy and to expand national coverage by including new indications. The Memo now updates NCD 20.4 again, aiming to provide guidelines that align more closely with the recommendations of professional organizations, practical application and current, evidence-based research. With publication of the Memo, NCD 20.4 is effective for claims with dates of service beginning February 15, 2018, the effective date of the Memo. CMS will be updating the Medicare National Coverage Determination Manual (Pub. 100-3) of the CMS Internet-Only Manual to reflect the changes in the Memo, as well as issuing instructions to the Medicare Administrative Contractors ("MACs") related to claims processing. To date, a Change Request has not yet been issued to the MACs identifying the implementation date for the claims processing instructions. This article discusses the most significant areas of change to NCD 20.4 governing covered indications for reimbursement of ICDs.

DISCUSSION

Waiting Period Exceptions

Importantly, NCD 20.4 now includes two carve-outs to the waiting period requirements for implantation of an ICD. Prior to the actions delineated in the Memo, hospitals could not implant ICDs within 40 days of an MI or 90 days of a CABG or PTCA. NCD 20.4 includes changes as follows:

- Adding an exception to the waiting periods for patients meeting CMS coverage requirements for cardiac pacemakers and who otherwise meet the criteria for an ICD; and
- Adding an exception to the waiting periods for patients with an existing ICD and qualifying replacement due to end of battery life, elective replacement indicator ("ERI") or device/lead malfunction.

Since violations of the aforementioned 40- and 90-day waiting periods were a predominant issue raised by the DOJ investigation, the new

exceptions provide some relief where patients may justifiably receive ICD implantations without having to wait the full 40- and 90-day period. For instance, patients who meet requirements for both a cardiac pacemaker for pacing needs and a defibrillator would now be allowed to receive the ICD without having to undergo a second procedure for the defibrillator after the expiration of the waiting periods.

Patient-Related Covered Indications

NCD 20.4 also includes a number of revisions to patient-related covered indications used to determine eligibility for ICDs. These indications assist in the determination of whether a patient would be eligible to receive an ICD. NCD 20.4 incorporates the following changes:

- Adding cardiac magnetic resonance imaging to the list of diagnostic imaging studies that can evaluate left ventricular ejection fraction;
- Requiring patients with severe non-ischemic dilated cardiomyopathy, but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, to be on optimal medical therapy ("OMT") for at least three months; and
- Removing the Class IV heart failure requirement for cardiac resynchronization therapy ("CRT").

CMS references CRT devices in the Memo because they contain defibrillator functions, but CMS removed the CRT requirement and explicitly stated that CRT devices were outside the scope of the Memo, making NCD 20.4 inapplicable to such devices. The Memo notes that coverage determinations for CRT devices are not subject to an NCD and are currently made by local Medicare contractors. In contrast, CMS expressly chose not to change the language regarding OMT despite comments expressing concerns about those requirements. CMS noted the importance of tailoring OMT to each particular patient and cited evidence for their rationale in maintaining the three-month waiting period.

Shared Decision-Making and Evidence-Based Decision Tool

CMS has included a completely new requirement in NCD 20.4 for a patient shared decision-making ("SDM") interaction for certain patients, including patients receiving an ICD for primary prevention who do not have an existing ICD. SDM, in conjunction with the use of an evidence-based decision tool (“Decision Tool”), is intended to assist patients and their physicians or other non-physician practitioners, such as a nurse practitioner or clinical nurse specialist, in sharing information about treatment options; risks and benefits; and patient preferences and values with patients, their families and significant others. The SDM and Decision Tool are intended to ensure that clinicians adopt a shared decision-making approach in which treatment decisions are based not only on the best available evidence but also on the patients’ health goals, preferences and values. To provide flexibility for this indication, CMS has specifically noted that the SDM encounter may occur at a separate visit.

Although CMS does not require the use of any specific Decision Tool, the Memo includes an example of a Decision Tool, funded by the National Institutes on Aging and the Patient-Centered Outcomes Research Institute and developed by the University of Colorado School of Medicine, for patients with heart failure considering an ICD who are at risk for sudden cardiac death. CMS also references this Colorado Program for Patient Centered Decisions website developed to lead patients through information on ICDs in a step-by-step fashion. The information on ICDs is designed to increase patients’ knowledge of their medical condition and the risks and benefits of available treatments and to empower patients to become more involved in the decision-making process.

Registry Requirement

NCD 20.4 no longer includes an ICD registry data collection requirement, which dates back to 2005 when CMS included a mandate for an ICD registry to gather data tracking ICD effectiveness. Previously, hospitals collected and submitted voluminous data to the ICD registry about patients receiving ICDs. The data was used by CMS to generate and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. Recently, the public comments that CMS received during the NCD review process indicated that a number of responders considered the requirement no longer necessary, especially because many of the questions about the effectiveness of ICDs could be answered based on the existing data. CMS took these views into account and expressed agreement with health care providers, discontinuing the registry data collection requirement and reducing the burden borne by hospitals.

TAKEAWAYS

For the first time in over 13 years, CMS has updated NCD 20.4 governing the implant of ICDs. Given recent history with the national DOJ investigation and associated settlements, health care providers should recognize the importance of these enumerated ICD coverage indications and take changes in NCD 20.4 to heart. While the impact of changes discussed in the Memo are effective immediately, MACs must wait for further technical instructions from CMS before updating claims processing software.

Hospitals and physicians who implant ICDs should assess their procedures and evaluative criteria associated with ICDs to ensure that they are in compliance with all covered indications in NCD 20.4. This may include developing or revising existing ICD implant Screening Tools and evaluating changes in practice given the exceptions to the 40- and 90-day waiting periods. If they are not already doing so, providers should quickly implement the SDM encounter processes along with an evidence-based Decision Tool. In the climate of increased scrutiny, especially after the large number of significant false claims settlements reached in recent years, hospitals should understand and implement compliance practices, including auditing and monitoring to ensure compliance with NCD 20.4.

If you have any questions or would like additional information about this topic, please contact:

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