Clear As Mud: CMS Coverage Requirements for Implantable Defibrillators

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Today hospital billing for implantable defibrillators is the subject of a nationwide government investigation and of many internal hospital audits prompted by the government inquiry. According to DOJ attorneys, CMS asked them to review hospital Medicare claims to determine whether certain defibrillator procedures were performed too soon after the patient experienced a major cardiac event such as a heart attack. For some hospitals, hundreds of claims involving potentially significant liability are under scrutiny, and many of them (up to 25% or more) involve patients who experienced ventricular tachycardia, an abnormally rapid heart rhythm.

The government should remove ventricular tachycardia cases from its investigation, because the Medicare coverage rules for such cases are as clear as mud, see Table 2 below, and ambiguous regulations are fatal to allegations of False Claims Act liability. See, e.g., United States v. Prabhu, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) (“Claims are not ‘false’ under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government”).

DOJ Investigation

In March 2010, the United States Department of Justice began an investigation of hospital billing for ICDs that continues today. The Justice Department initiated the inquiry by issuing Civil Investigative Demands under the False Claims Act to numerous hospitals, hospital chains, and device manufacturers. The probe broadened during the last year as DOJ delivered letters of inquiry to additional hospitals stating their defibrillator claims were also under review. At this writing, the government has not resolved this matter with any of the hospitals involved in the inquiry.

DOJ attorneys cite a Medicare National Coverage Determination (NCD § 20.4) that sets forth nationwide coverage criteria for ICDs; they contend that preliminary claims data indicates that some hospital claims were excluded from coverage under the NCD based on certain timing restrictions that apply only to ICDs for the primary prevention of sudden cardiac death.

Primary Versus Secondary Prevention

When a patient’s health condition places him or her at significant risk of sudden cardiac death, but the patient has not yet experienced a life-threatening cardiac arrest or arrhythmia, the ICD is said to be implanted for the “primary prevention” of sudden cardiac death. By contrast, an ICD

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is implanted for “secondary prevention” when the patient has previously experienced a life-threatening cardiac event, and the ICD is intended to prevent a second episode. (The primary / secondary terminology serves mainly as a shortcut to describe patient history, but, as shown here, it’s a problematic shortcut that probably should be abandoned in favor of simply describing the patient history.)

Primary prevention ICDs must meet more extensive criteria for Medicare coverage. In particular, Medicare will not cover a primary prevention ICD if the patient has experienced an acute myocardial infarction (MI) within the past 40 days or a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) procedure within the past 3 months. See NCD § 20.4 (indications #3-8 relate to “primary prevention of sudden cardiac death” and must meet these calendar restrictions among other conditions of coverage).

The government is examining claims that appear to violate these timing restrictions, but they have left it to hospitals to figure out which of their claims involve primary prevention ICDs, which must meet these timing restrictions, and which claims do not. Thus, categorizing the claims appropriately is an essential component of a hospital’s response to the investigation.

**CMS Publications**

CMS traditionally treated ventricular tachycardia as a secondary prevention diagnosis, but more recent guidance has confused things. Today CMS publications sometimes characterize this diagnosis as “primary prevention” and other times characterize it as “secondary prevention.” This inconsistent treatment undermines the government’s effort now to box any of these claims into the primary prevention category. (While this paper addresses ventricular tachycardia, ambiguity also surrounds CMS’s treatment of other conditions too, e.g., myocardial infarction, in the context of defibrillator coverage.)

Hospital billing for defibrillators is governed by the Medicare Claims Processing Manual (“the Claims Manual”), and Medicare coverage policy is set forth in § 20.4 of the National Coverage Determination Manual. With respect to ventricular tachycardia, these publications are inconsistent with each other, the NCD is internally inconsistent, and both the Claims Manual and NCD conflict with separate CMS-approved instructions for hospitals entering ICD claims data in a mandatory data registry. See Table 2.

**Claims Manual**

Whether the patient’s status is inpatient or outpatient, the Claims Manual sets forth coding and billing requirements for the hospital. See Claims Manual, Chapter 32. § 270-Claims Processing for Implantable Automatic Defibrillators (Pub. 100-04). For patients receiving a defibrillator for primary prevention, the hospital should enter patient data in a national data registry approved by CMS as a condition of Medicare coverage. See NCD, § 20.4 Thus CMS explains in the Claims Manual which claims are for primary prevention and which ones are for secondary prevention.

Since at least March 2005, ventricular tachycardia has appeared and remains on a list in the Claims Manual of diagnosis codes that identify secondary prevention cases:

**Secondary Prevention**

427.1 Ventricular tachycardia
427.41 Ventricular fibrillation
427.42 Ventricular flutter
427.5 Cardiac arrest
427.9 Cardiac dysrhythmia, unspecified
V12.53 Personal history of sudden cardiac arrest

Id. § 270.2 (excerpt of list is quoted here) (emphasis added). The Claims Manual explains that these and other types of secondary prevention cases need not be entered in the data collection system.

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The Government assumes the NCD is the exclusive basis for coverage for ICDs, but that assumption has been questioned. See Jesse A. Witten & David M. Glaser, “The Government’s Investigation of Medicare Billing for ICDs is Based on a Flawed Legal Premise,” BNA Health Care Fraud Report, June 1, 2011.
CMS has stated that when one of the above diagnosis codes appears on a claim, “these codes identify a patient receiving the device as secondary, not primary, prevention of sudden cardiac arrest.” See Pub. 100-04, Transmittal 497, dated March 8, 2005 (regarding MA Plan billing). Furthermore, CMS has stated defibrillators are “for the primary prevention of sudden cardiac arrest” when there is “no history of induced or spontaneous arrhythmias,” which includes ventricular tachycardia. Id.; repeated in Pub. 100-04, Transmittal 819, Jan. 27, 2006. By inference, therefore, a history of ventricular tachycardia indicates secondary prevention. CMS also has explained that the “primary prevention population is identifiable on claims through the absence of” the ICD-9 claims listed above, including ventricular tachycardia. See Pub. 100-04, Transmittal 497, dated March 8, 2005.

Based on the plain language of the Claims Manual and CMS’s instructions, hospital billing and coding personnel reasonably may assume that a patient diagnosed by a physician with ventricular tachycardia has a secondary prevention indication. In that case, the hospital would have no reason to question whether the case meets the timing restrictions that apply only to primary prevention cases. The NCD, however, is inconsistent with that approach.

**NCD Manual**

A host of inconsistencies arise when one attempts to determine whether ventricular tachycardia currently qualifies as a primary or secondary prevention indication under NCD § 20.4. As the first point of inconsistency with the Claims Manual, the NCD does not use the word ventricular tachycardia. It uses the term ventricular tachyarrhythmia, and this article assumes that CMS intends for ventricular tachyarrhythmia to encompass ventricular tachycardia as well as ventricular fibrillation, based on clinical practice.

Only a clinician (or a lawyer assisted by one) can begin to interpret the language of NCD § 20.4 for implantable defibrillators. CMS last updated the policy more than six years ago in March 2005. Medical guidelines developed by expert clinicians at the behest of cardiovascular professional societies have long since evolved, and the NCD is also rife with internal inconsistencies and ambiguity (articles for another day). In view of the medical complexity of this NCD, hospitals necessarily must rely on their medical staff to determine medical necessity. Cf. Edwards, 937 F.2d at 583.

### NCD’s Historical Treatment of Ventricular Tachycardia

Beginning in 1986 with the first coverage determination for implantable defibrillators, CMS treated inducible ventricular tachycardia as an approved indication that was not subject to the 40-day / 3-month calendar delays following a cardiac event, as later implemented for certain indications. The Coverage Issues Manual (CIM § 35-85) then described the covered indication as a “documented episode of life-threatening ventricular tachyarrhythmia,” and so long as it was “inducible” in an electrophysiology study, the defibrillator was covered as a treatment of last resort.

In 1991, CMS removed the “last resort” stipulations and provided ICD coverage for patients who experienced a “documented episode of life-threatening ventricular tachyarrhythmia . . . .” In 1999, CMS maintained the foregoing language but also added a new, separately listed indication (#2) for “ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause.”

Thus, between 1986 and 2003 (about 17 years), CMS covered ICDs for inducible ventricular tachycardia when the stated conditions were met, but the coverage policy did not impose the calendar timing restrictions now at play in the DOJ investigation.

In October 2003, CMS expanded coverage by adding new indications to CIM § 35-85. Newly added Indication #4 now purported to cover “inducible, sustained” ventricular tachyarrhythmia when the patient had coronary artery disease and met several other criteria. However, Indication #4 applied only if the patient did not have a myocardial infarction during the 4 weeks
prior to defibrillator insertion. (See discussion below of MADIT I clinical trial.)

Thus, CMS first introduced a calendar delay in 2003 and attached it to an indication for inducible ventricular tachycardia. But the historical language covering inducible ventricular tachyarrhythmia ("either spontaneous or induced, not due to a transient or reversible cause") remained in CIM § 35-85 as Indication #2, and that original indication still was not subject to the 4-week delay after myocardial infarction.

Thus, the seeds of confusion were planted in 2003, and they began to sprout in 2005 when CMS again modified and expanded the NCD.

NCD’s Current Treatment of Ventricular Tachycardia

In January 2005, CMS last revised the coverage policy. See NCD § 20.4. As relevant here, the current NCD supplemented the criteria for the ventricular tachyarrhythmia indications and for the first time introduced the term “primary prevention.”

The current NCD describes a total of 9 covered indications for defibrillator implants. Two of them -- #2 and #4 -- apply to ventricular tachycardia cases.

TABLE 1

The NCD states that indications #3-8 are for “primary prevention of sudden cardiac death,” and imposes the 40-day / 3-month timing restrictions of interest to DOJ as a condition of coverage for those indications. Thus, Indication #4 falls in the primary prevention category.

The NCD makes no mention of “secondary prevention,” but one infers that Indication #2 is for secondary prevention, given it is not described as a primary prevention indication, and this indication existed long before CMS introduced the primary prevention concept in the NCD.

In short, the NCD now identifies inducible ventricular tachycardia as a secondary prevention indication in #2, while identifying it as a primary prevention indication in #4. Because #4 is a primary prevention indication, the coverage criteria include the timing restrictions that DOJ in investigating -- no MI within 40 days and no CABG or PTCA within the last 3 months. But if #2 applies, the claim does not have to satisfy those restrictions.

Life might be easier for one analyzing whether a case is a #2 or a #4 -- and thus whether it is in or out of the lion’s den -- if the other health conditions identified in these indications were mutually exclusive, but they are not. The language makes them sound like different indications. For instance, "spontaneous" ventricular tachycardias qualify only under #2 and are secondary prevention cases.

However, a patient with “inducible” ventricular tachycardia who meets the criteria for Indication #4 also likely meets Indication #2 under the language of the NCD. See Table 1. For example, the patient, who may have coronary artery disease, a prior MI and an LVEF less than 0.35, has inducible sustained ventricular tachycardia that is not associated with an acute MI and is not due to a transient or reversible cause. This history is not uncommon. In our opinion, this patient qualifies for #2 as well as #4 under the explicit language of the NCD. Under the NCD criteria for #2, there is no restrictive or limiting language regarding the presence or

<table>
<thead>
<tr>
<th>NCD § 20.4</th>
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| 2. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause (effective July 1, 1999).

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4. Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) ≤ 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.) [Must also satisfy other criteria for primary prevention indications]
absence of coronary artery disease, a prior MI, level of ejection fraction, or any other chronic condition. In this scenario which qualifies for #2, there is also no Medicare requirement for a delay of 40 days after myocardial infarction and 3 months after CABG or PTCA, whereas the requirement does exist under #4. The NCD is internally inconsistent, and for that reason, DOJ should steer clear of both spontaneous and induced ventricular tachycardia cases.

An element common to both #2 and #4 is an episode of induced sustained ventricular tachycardia or ventricular fibrillation, where the term “induced” refers to the deliberate demonstration of the specific arrhythmia by programmed electrical stimulation during an electrophysiological study. Although CMS added #4 in 2003 based on clinical trial data, such as the MADIT I trial, the criteria described in #4 do not fully conform to the characteristics of that trial or other confirmatory studies. See Moss AJ, Hall WJ, Cannom DS, et al., Improved Survival With An Implanted Defibrillator In Patients With Coronary Artery Disease At High Risk For Ventricular Arrhythmia, N Engl J Med 1996; 335:1933-1940. Moreover, the 2003 Decision Memorandum issued by CMS, which explains the coverage expansion that year, discusses the MADIT I trial in detail; however, the Memorandum does not address the decision criteria for assigning an ICD implant for induced sustained ventricular tachycardia to either #2 or #4. See CMS Decision Memorandum, CAG-00157N (June 6, 2003).

Thus, CMS simply fails to distinguish between an episode of induced sustained ventricular tachycardia assigned to indication #4 (primary prevention) and one that is assigned to indication #2 (secondary prevention). Yet, one purports to be subject to the timing criteria, whereas the other is not.

NCDR Registry

To compound the problem, both of the foregoing CMS publications are inconsistent with the CMS-approved data registry for ICD patients during the period covered by the DOJ inquiry. See Table 2 below. As a condition of coverage of primary prevention cases, CMS requires hospitals to enter patient data in the National Cardiovascular Data Registry (NCDR) for implantable defibrillators. See www.NCDR.com (FAQs for “CMS Mandated ICD Registry”).

The NCDR is a data repository where hospitals record patient data and obtain quality of care information based on benchmarking with peers. See www.NCDR.com. The ICD portion of the Registry is sponsored by the American College of Cardiology Foundation (ACCF) and the Heart Rhythm Society, and it is the only Registry approved by CMS for mandatory data collection relating to primary prevention defibrillators. (DOJ has retained the Heart Rhythm Society as consultants in the ICD investigation.)

The NCDR ICD Registry provides a “data dictionary” to hospitals. The first version of this dictionary was effective until early last year.

Version 1.08

From inception to early 2010, the dictionary categorized ventricular tachycardia as a primary prevention indication only when it was “inducible” during an electrophysiologic study, whereas “spontaneous” ventricular tachycardia was defined as a secondary prevention. See ACCF, ICD Registry, Data Dictionary, version 1.08, May 23, 2006. For most of the period covered by the DOJ investigation, therefore, the NCDR ICD Registry’s data dictionary distinguished between “induced” and “spontaneous” ventricular tachycardia.

By contrast, either inducible or spontaneous ventricular tachycardia could qualify as a secondary prevention diagnosis under the NCD or the Claims Manual. Again, a hospital was left to confront a bewildering set of inconsistent instructions about ventricular tachycardia.

Version 2.1

But wait, there’s more. The NCDR ICD data dictionary changed in early 2010. Now, version 2.1 of the data dictionary provides that sustained ventricular tachycardia is never a primary prevention indication,
regardless of whether it is induced or spontaneous. According to the Registry, primary prevention refers to “individuals who are at risk for but have not yet had an episode of sustained ventricular tachycardia.” See ACCF, ICD Registry, Data Dictionary, version 2.1, February 23, 2010 (emphasis added). Secondary prevention includes patients who have “survived” sustained ventricular tachycardia, whether it occurs spontaneously or is induced in an electrophysiology laboratory.

Summary of Current Guidance

Thus, we have come full circle. Today, the NCDR ICD Registry data dictionary and the Claims Manual are consistent in stating, at least with respect to a diagnosis of sustained ventricular tachycardia, that the diagnosis falls squarely and without question in the secondary prevention category, irrespective of whether it is spontaneous or inducible.

If only the NCD were so straightforward, we might have clear guidance at this point. But the NCD still leaves us hanging, with inducible ventricular tachycardia sometimes classified as a secondary prevention indication and sometimes a primary one, and often the diagnosis falls in both categories, because the patient meets criteria for both indications #2 and #4 in the NCD. See Table 2.

For a typical hospital, this regulatory ambiguity -- which was even worse before the 2010 change in the data dictionary -- together with the necessity of relying on the implanting physician’s medical judgment should prompt the Justice Department to remove ventricular tachycardia cases from this investigation.

No False Claims Act Liability

The False Claims Act, 31 U.S.C. § 3729(a)(1), creates liability for a hospital that “knowingly presents” a false claim for payment to Medicare, among other grounds. However, a claim is not “false,” and a hospital cannot know of any falsity, when the claim is consistent with a reasonable interpretation of the regulations governing the claim. See, e.g., United States ex rel. Glass v. Medtronic, Inc., 957 F.2d 605, 608 (8th Cir. 1992) (a statement cannot be “false” or “fraudulent” under the FCA when the statement is consistent with regulations governing program); Prabhu, 442 F. Supp. 2d at 1029 (“A Defendant does not knowingly submit false claims when he follows Government instructions regarding the claims.”) (cit. omitted).

Here, CMS cannot at once instruct hospitals in the Claims Manual that a ventricular tachycardia diagnosis code is always for secondary prevention and simultaneously assert a violation based on a different premise in the NCD, which itself is susceptible to more than one reasonable interpretation. The law is well settled that “acting according to a reasonable interpretation” of ambiguous regulations “does not qualify as knowing or reckless disregard for falsity under the FCA." United States ex rel. Hixson v. Health Mgmt. Sys., 657 F. Supp. 2d 1039, 1057 (S.D. Iowa 2009) (citing United States ex rel. K & R Ltd. P’ship v. Mass. Housing Fin. Agency, 530 F.3d 980 (D.C. Cir. 2008) (affirming summary judgment on relator’s FCA claim where allegation of fraud depended on interpretation of ambiguous mortgage note and both parties interpretations were plausible); and comparing Safeco Ins. Co. of Am. v. Burr, 551 U.S. 47, 70, n. 20 (2007) (noting, in the context of the Fair Credit Reporting Act, that “where… the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one interpretation as a knowing or reckless violator").

FCA liability is particularly unwarranted in the context of ambiguous regulations coupled with the exercise of sound medical judgment and the delivery of needed services to Medicare beneficiaries. See, e.g, Bergeron v. Shalala, 855 F. Supp. 665, 668 (D. Vt. 1994) (in evaluating whether a patient meets criteria for Medicare coverage, the Secretary of HHS “is expected to place significant reliance on the informed opinion of a treating physician and apply "some extra weight" to the opinion, or supply "a reasoned basis, in conformity with statutory purpose, for declining to do so.") (cit
State of N.Y. on Behalf of Holland v. Sullivan, 927 F.2d 57, 60 (2d Cir. 1991); United States v. Krizek, 859 F. Supp. 5, 10 (D.D.C. 1994) ("[Providers] should be appropriately reimbursed for services legitimately provided. They should be given clear guidance as to what services are reimbursable. The system should be fair."); aff'd in part & remanded, 111 F.3d 934 (D.C. Cir. 1997).

Conclusion

In summary, DOJ cannot prove that a hospital knew, in ventricular tachycardia cases, that its defibrillator claims (or certifications associated with them) were false in an ambiguous regulatory environment, and when a hospital relied in good faith on the treating physicians’ judgment that the defibrillator was a medically necessary response to ventricular tachycardia. See, e.g., Prabhu, 442 F. Supp. 2d at 1026 (finding “general confusion regarding the appropriate circumstances under which” certain tests could be billed, and concluding that “claims are not ‘false’ under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government”) (citing many cases); United States ex rel. Swafford v. Burgess Med. Ctr., 98 F. Supp. 2d 822, 831-32 (W.D. Mich. 2000) (a “legal dispute” over the meaning of regulatory terms is insufficient to establish FCA liability), aff'd, 24 Fed. Appx. 491 (6th Cir. 2001); Landau v. Lucasti, 680 F. Supp. 2d 659, 669 (D.N.J. 2010) (ambiguity in Medicare regulations, during a period before an amendment clarified them, was “fatal to Plaintiff's quest for damages” under the FCA for claims submitted during the pre-amendment period).
## TABLE 2

### Diagnosis of Ventricular Tachycardia

<table>
<thead>
<tr>
<th>Source</th>
<th>Primary Prevention</th>
<th>Secondary Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS Claims Processing Manual, Ch. 32, § 270.2 (March 2005 - present)</td>
<td>Never</td>
<td>Always</td>
</tr>
<tr>
<td>NCD § 20.4 (Oct. 2003 - present) (current version is quoted here)</td>
<td>Yes, under indication #4: “Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) ≤ 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)” [Must also satisfy other criteria for primary prevention indications]</td>
<td>Yes, under indication #2: “Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause”</td>
</tr>
<tr>
<td>NCDR Data Dictionary, v.1.08, Seq. #3505 (2005 - Feb. 2010)</td>
<td>Yes, if induced: “patients who have never experienced syncope . . . but have inducible ventricular tachycardia during” EP study</td>
<td>Yes, if spontaneous: “patients who have already experienced a spontaneous life-threatening ventricular arrhythmia” or syncope due to same</td>
</tr>
<tr>
<td>NCDR Data Dictionary, v.2.1, Seq. #4130 (Feb. 2010 - present)</td>
<td>Never: “Individuals who are at risk for but have not yet had an episode of sustained ventricular tachycardia”</td>
<td>Always: “patients who have survived . . . sustained ventricular tachycardia”</td>
</tr>
</tbody>
</table>