Department of Justice ICD Investigation

Medical Review Guidelines/Resolution Model

These medical review guidelines and this resolution model (collectively "Resolution Model") have been developed to resolve claims related to DOJ's Implantable Cardioverter Defibrillator ("ICD") investigation, and are applicable only to this investigation.

It must be emphasized that CMS National Coverage Determination ("NCD") 20.4 governs the payment of ICDs by Medicare. The Resolution Model is <u>not</u> CMS policy. It does not replace, update or interpret NCD 20.4 and should not be relied upon or utilized in any manner to determine whether an ICD is payable by Medicare.

The Resolution Model is to be used solely for the purpose of facilitating the settlement of claims arising out of DOJ's ICD investigation, is subject to F.R.E. 408, and is subject to final DOJ authorization.

DOJ Resolution Model Summary Chart

		DAMAGES		
		Single Damages[1]	X	Multiplier[2]
I.	**Covered by the NCD and/or Excluded from this Investigation:**			
	Covered Under NCD Indication #1	NA		NA
	Covered Under NCD Indication #2	NA		NA
	Covered Under a Clinical Trial	NA		NA
	No Medicare Payment	NA		NA
II.	**DOJ No Enforcement Categories (Buckets):**			
	No MI (Proper Code or No Payment Change)	None		None
	Pacemaker	None		None
	CRT-D	None		None
	Replacement	None		None
	Technical Violation (Late Stage Implants)	None		None
	Syncope	None		None
	Bridge to Transplant	None		None
	NCD Indication #3 (Familial/Inherited Conditions)	None		None
III.	**DOJ Category - With Enforcement:**			
	Previously Qualified	YES		YES
IV.	**Coding Error (Without Repeating Patterns):**			
	No MI (Coding Error With Payment Difference)	YES		YES
	No ICD (Coding Error)	YES		YES
	No CABG/PTCA (Coding Error)	YES		YES
V.	**Not Covered By NCD or DOJ Categories**	YES		YES
VI.	**Not Medically Indicated**	YES		YES

[1] Single damages will be the difference between what the facility was paid on each claim and what the facility should have been paid on each claim without the ICD code(s) and related charges ("damages"). It will be necessary to assign the correct DRG in order to calculate this difference. Outlier payments may also need to be recalculated.

[2] The multipliers in this Resolution Model will be determined during discussions with each facility and will be based upon many factors, including, but not limited to, the categories above, patient harm, patterns, compliance efforts and effectiveness, ICD registry submissions and knowledge evidence ("multiplier").

I. NCD Covered Indications 1 & 2

If a claim meets the criteria of Indications 1 or 2 as set forth in the NCD and/or satisfies the criteria set forth herein, the claim will be excluded from this investigation.

A. NCD Indication #1

The patient had a documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause. If the VF occurred due to an acute myocardial infarction (MI) or transient myocardial ischemia due to coronary artery lesions, for which the patient was a candidate for a percutaneous coronary intervention (PCI) (also referenced as PTCA herein) or coronary artery bypass graft (CABG), the cause of the VF would be considered reversible.

Documentation Requirements[3]: There is documentation in the medical record that the patient had a cardiac arrest due to VF. Optimally, there will be cardiac monitor recordings (telemetry strips) in the medical record which show the VF. There should be documentation of the arrest in the form of a "code report" or a similar record. If the arrest occurred outside the hospital (in the field), there will likely be no documentation other than a statement made by the first responders. If there is documentation that the patient required defibrillation by an automatic external defibrillator, it will be considered to be corroborating documentation. If the treating physician documented that the VF was due to a transient or reversible cause (including, but not limited to, electrolyte imbalances, drugs, ischemia, or acidosis), or based upon, for example, findings from a cardiac catheterization report or revascularization procedure note (e.g., revascularization of a "culprit lesion") and this cause was treatable, the clinical reviewer will find that the patient's presentation does not meet NCD Indication #1.

[3] In addition to the specific clinical documentation requirements listed throughout, the Resolution Model's general documentation guidelines are:

Independent Documentation: Examples include a procedure report, an ECG or monitor strip showing dysrhythmia, or test result reports. While a clinical reviewer should use independent documentation to verify documented conditions when possible, it may not always exist in the medical record. In these instances, the clinical reviewer may use corroboration as verification of clinical conditions as outlined below.

Corroboration: Typically, significant clinical events that occur in a hospital or when the patient is attended by clinical personnel are documented by multiple care givers in various medical record entries. For instance, if a patient has an episode of VF, one may see documentation from the nurse and/or monitor technician, documentation from the physician, and perhaps new orders for a change in clinical care. If there is physician documentation in the patient record and there is no independent documentation of an event, the presence of corroborating documentation by the nurse or other care giver, or new orders to treat the condition, may be sufficient to confirm that the event/condition occurred. Simple reiteration of clinical findings would not be considered corroborating documentation.

The patient presented with documented or presumed out-of-hospital VF and acute MI, and the medical record supports that it is not possible to determine, or difficult to determine with certainty, whether the VF or the MI was the primary precipitating event. Revascularization via CABG or angioplasty (with or without a stent) does not automatically mean that the VF was not the primary event.

Documentation Requirements: The documentation should include statements by the original treating physician, the ED physician, or in-hospital treating physician of the patient's condition at presentation. Optimally, there will be an emergency rescue report or cardiac rhythm strips which support the diagnosis of VF. If there is an emergency rescue response to an out-of-hospital cardiac arrest or an arrest defibrillated by an automatic external defibrillator (AED), there will likely not be any supporting cardiac rhythm strips. This should be specifically noted in any medical record review.

Documentation which supports that the VF event was the primary event includes, but is not limited to, studies showing that the VF was caused by cardiac scar tissue or substrate. There should not be documentation which associates the VF event with reversible causes, such as electrolyte imbalances, drugs, ischemia, or acidosis (this is not an exhaustive list).

B. NCD Indication #2

The patient had documented sustained ventricular tachyarrhythmia(s) (VT). Patients with inducible sustained VT during an electrophysiology (EP) study are also included in this definition. The sustained VT event must not be "associated with" an acute MI (defined as occurring within 48 hours of the MI, beginning at triage time) and must not be due to a transient or reversible cause. If the VT occurred due to an acute MI, or coronary artery lesion which made the patient a candidate for revascularization, or occurred within 12 hours of a percutaneous transluminal coronary angioplasty (PTCA) or CABG, the cause of the VT would be considered "transient or reversible."

The EP study should be far enough removed from the index event to avoid associated symptoms and done at least 96 hours post-MI or post revascularization.

Documentation Requirements: There is documentation in the clinical record that the patient had a VT event that was not due to a transient or reversible cause and that VT event was sustained (lasted at least 30 seconds), or caused the patient to experience syncope. Signs and symptoms of hemodynamic instability (i.e., near syncope, drop in blood pressure greater than 20 mmHg from baseline, chest pain) are not to be considered sustained VT. If the treating physician documented that the VT was due to a transient or reversible cause, based upon, but not limited to, findings from a cardiac catheterization report or revascularization procedure note (e.g. revascularization of a "culprit lesion") and this cause was treatable, the clinical reviewer will find that the patient's presentation does not meet NCD Indication #2.

Documentation of the VT should be supported by ECG or cardiac monitor strips. If these do not exist in the record, there should be corroborating evidence that the VT event occurred and that it was sustained (lasting at least 30 seconds or causing hemodynamic collapse). If there is any documentation which states that the VT was due to a treatable cause, e.g., ischemia, electrolyte imbalance, acidosis, etc., this indication is not met. If the VT was induced at EP study, it will be considered sustained if it lasts at least 30 seconds or if it required termination via cardioversion/defibrillation or antitachycardic pacing. Documented evidence of VT at EP study should be in the EP procedure report. Independent documentation of the rhythm in the EP lab is not required, but is often corroborated in the EP log.

The patient presented with documented or presumed out-of-hospital sustained VT and acute MI, and the medical record supports that it is not possible to determine, or difficult to determine with certainty, whether the sustained VT or the MI was the primary precipitating event. Revascularization via CABG or angioplasty (with or without a stent) does not automatically mean that the sustained VT was not the primary event.

Documentation Requirements: The documentation should include statements by the original treating physician, the ED physician, or in-hospital treating physician of the patient's condition at presentation. Optimally, there will be an emergency rescue report or cardiac rhythm strips which support the diagnosis of sustained VT. If there is an emergency rescue response to an out-of-hospital cardiac arrest or an arrest defibrillated by an automatic external defibrillator (AED), there will likely not be any supporting cardiac rhythm strips. This should be specifically noted in any medical record review.

Documentation which supports that the sustained VT event was the primary event includes, but is not limited to, studies showing that the sustained VT was caused by cardiac scar tissue or substrate. There should not be documentation which associates the sustained VT event with reversible causes, such as electrolyte imbalances, drugs, ischemia, or acidosis (this is not an exhaustive list).

II. DOJ No Enforcement "Categories" (also referred to as "Buckets")

During the course of this investigation, certain categories of ICD implants for primary prevention of sudden cardiac death have been identified (based upon Indications 3-9 of the NCD). The no enforcement categories include ICD implants that, although potentially violative of NCD time frames (or waiting periods), will not be enforced in this Resolution Model (with the exception of the Previously Qualified category) pursuant to DOJ discretion in False Claims Act enforcement. The Categories are listed below.

1. No MI (Appropriately coded or without difference in payment)

An implant in this category is one in which coding indicated that the patient had an acute MI followed by an ICD implant within the 30/40 day prohibited time frame. Upon review, it has now been determined that the patient did not, in fact, have an acute MI.

The medical record documentation supports that the coded MI was not a "true" MI. In some of these cases, there is conflicting documentation in the medical record that an acute MI occurred and the coding of the MI was appropriate. In others, a MI was not appropriately coded, but there is no difference in the payment without the MI code.

Documentation Requirements: The reviewer should document the likely reason for the elevated troponin. Examples of this are when the admitting physician or ED physician may document that a MI occurred, but there is clinical evidence that no MI occurred or there is no confirmation of the MI in the body of the record or discharge summary; there is a troponin elevation with no ECG changes and the patient has other clinical conditions which would have led to the elevated troponin levels (e.g., CHF, cardioversion, renal failure, prolonged tachycardia). (MI Cases Only)

The reviewer should document the peak troponin and the lab reference range. If CK-MBs were performed, these should also be documented. If CK-MBs are significantly elevated, this category would not apply.

2. Permanent Pacemaker (PPM)/Cardiac Resynchronization Therapy (CRT)

a) Patient qualifies for Permanent Pacemaker (PPM) and (other than the waiting periods) also qualifies for an ICD

This category was designed to prevent rigid enforcement where a patient otherwise would have undergone a PPM implantation procedure followed by—after the expiration of the 30/40 and/or 90 day prohibited time frames—subsequent procedures to explant the PPM and then implant an ICD. This patient meets all applicable medical guidelines and Medicare payment rules for PPMs and ICDs other than the 30/40 and/or 90 day prohibited time frames.

The patient's clinical condition supports the need for a permanent pacemaker (PPM) and there is documented evidence that the patient otherwise qualified for an ICD. The

patient's LVEF must not exceed 35% (measured at or near the end of the prohibited time frames) to qualify for both a PPM and an ICD.

If the patient has a clinical condition that requires a PPM but the patient does not meet indications for an ICD, that ICD is not covered by the NCD and does not fall within this category.

Documentation Guidelines: The medical record must support that the patient has a clinical condition requiring the use of a PPM and meets the NCD for Permanent Pacemakers and the ACC/AHA/HRS Guidelines. Examples include: tachy-brady syndrome, junctional rhythm, complete heart block, patients with bradycardia who need support for beta blocker therapy.

b) Patient qualifies for Cardiac Resynchronization Therapy (CRT) and (other than the waiting periods) also qualifies for an ICD

This category was designed to prevent rigid enforcement where a patient otherwise would have undergone a CRT implantation procedure followed by—after the expiration of the 30/40 and/or 90 day prohibited time frames—subsequent procedures to explant the CRT-P and then implant a CRT-D. This patient meets all applicable medical guidelines and Medicare payment rules for CRTs and ICDs other than the 30/40 and/or 90 day prohibited time frames.

The patient's clinical condition supports the need for cardiac resynchronization therapy and there must be documented evidence that the patient otherwise qualifies for an ICD. The patient's LVEF must not exceed 35% (measured at or near the end of the prohibited time frames) to qualify for both a CRT-P and an ICD.

It is reasonable for patients who require a CRT device for management of their heart failure, and who meet the ACC/AHA/HRS CRT guidelines, to have a CRT-D device implanted if their clinical history would otherwise qualify them for an ICD under the NCD, but for their intervening index event(s) (MI and/or revascularization).

Documentation Requirements: These recommendations presuppose optimal medical management with cardiac medications, such as ACE inhibitors, ARBs, beta blockers, and diuretics. If the patient cannot tolerate expected medical management, this information should be documented in the patient's medical record. The medical record supports that the patient is having signs and symptoms of heart failure which is not responding satisfactorily to medical management.

3. Replacement ICD (includes upgrade from one type of ICD to another)

Typically, this category will consist of a patient who already has an ICD and subsequently suffers a MI and/or undergoes a revascularization. During care for this event, it is determined that the ICD generator must be replaced because of, for example, end of battery life, elective replacement indicator (ERI), or device malfunction.

This category also includes an upgrade of an ICD from a single to a dual chamber ICD device or a single/dual chamber device to a CRT-D for a decline in the patient's

functional or clinical status. In other words, if a patient has a device that defibrillates and it is replaced with a device that does defibrillate, it may fit within this category.

If the patient is having a pacemaker changed to an ICD, this should not be categorized as replacement; rather it should be evaluated as a new device implantation. In other words, if a patient has a device which does not defibrillate and it is replaced with a device that does defibrillate, this category does not apply.

However, if the original ICD was also implanted within the 30/40 and/or 90 day prohibited time frames (i.e. it appears separately on your claims list), the initial implant must be evaluated and categorized as set forth in this Resolution Model.

Documentation Requirements: The medical record includes documentation which notes that the device is at ERI or that there is a device/lead malfunction.
There may be a report of device testing or ERI in the record, but often these records reside in the physician's office and are not part of the hospital record. The absence of these documents is not a reason to exclude the case from this category.

For device upgrades, there is documentation that the patient is having clinical signs and symptoms that are not addressed by the current device. This generally consists of patients with new onset of S-A node or A-V node dysfunction, junctional rhythms, or heart blocks which require both atrial and ventricular leads. In addition, the patient may have heart failure or other symptoms that require the initiation of biventricular pacing.

4. "Associated With"

An implant in this category is one in which the ICD was implanted because the patient had a sustained ventricular tachycardia which occurred more than 48 hours after an acute MI or more than 12 hours after a revascularization. Please refer to NCD Indication #2 in Section IB above.

5. Technical Violation (Late Stage Implant)

An implant in this category is one in which, although the ICD was otherwise indicated, it technically violated the NCD because it was implanted near the end of—but still during—the 30/40 and/or 90 day prohibited time frames.

Specifically, an ICD that was implanted between 30 and 40 days after an acute MI or between 67 and 90 days after a revascularization should be placed in this category.

There must be documented evidence that the patient otherwise qualified for an ICD. The patient's LVEF must not exceed 35% (measured at or near the end of the prohibited time frames).

Documentation Requirements: The date of the ICD implant must be documented as at least 30 days from the most recent MI or 67 days from a prior PTCA or CABG. The reviewer should obtain and provide the operative report for the CABG/PTCA and pertinent MI records.

6. Syncope

An implant in this category is one in which a patient with structural heart disease was implanted with an ICD within the 30/40 and/or 90 day prohibited time frames because of an episode of syncope that was likely cardiac in origin.

The medical record supports that the patient has a significant history of syncope that was caused or likely caused by a potentially lethal arrhythmia, even though there might be "timing violations."

Syncope is defined as loss of consciousness and postural tone caused by diminished cerebral blood flow. Documented pre-syncope, which is defined as episode of near-fainting which may include lightheadedness, dizziness, severe weakness, and/or blurred vision which may precede a syncopal episode, should not be considered as syncope in the context of this review.

Documentation Requirements: There is documentation that the patient has experienced one or more syncopal episodes over the past 12 months and that these episodes are likely associated with an episode of VT. There may be a family history of sudden death which supports this link. Documentation must be sufficient to rule out non-cardiac causes for syncope. Examples of documentation ruling out non-cardiac causes may include a neurological consult, a CT scan of the brain, a tilt table test, or orthostatic blood pressures. Although no specific test or group of tests is required to meet this DOJ category, a documented effort to rule out non-cardiac causes for the syncope is required. If it is suggested in the medical record that the syncope could be related to medications, seizures, or bradycardia and these issues were not ruled out as the cause of the current syncope, the case should not be placed in this category.

If there is an EP study and the EP study results in sustained VT or VT which must be terminated through cardioversion or antitachycardic pacing, the case meets NCD Indication #2 and is not reported in this category.

7. Bridge to Heart Transplant in Listed Candidates

An implant in this category is one in which a patient is on the UNOS (United Network for Organ Sharing) transplant list awaiting a donor heart, and was implanted with an ICD as a "bridge" to prolonged survival until a donor becomes available, notwithstanding that the implant violated the 30/40 and/or 90 day prohibited time frames.

The ICD is acceptable in transplant cases regardless of the timing of an acute MI or a revascularization procedure, as long as the patient otherwise qualifies for an ICD.

Documentation Guidelines: There should be documentation that the patient is a candidate for a heart transplant and is on the transplant list. Additionally, the patient has a cardiomyopathy that is not amenable to treatment.

8. Certain Familial and Inherited Conditions (NCD Indication #3)

An implant in this category is one in which a patient with one of the conditions defined by NCD Indication #3 was implanted with an ICD. There are no 30/40 and/or 90 day prohibited time frames applicable to Guideline-based indications for these primary diagnoses or their clinical manifestations.

The following list of specific disorders is currently recognized as most prevalent within this category. This list should not be considered exhaustive, as additional diagnoses may be added in the future.

- Congenital long- or short-QT interval syndromes
- Hypertrophic cardiomyopathy
- Arrhythmogenic right ventricular dysplasia/cardiomyopathy
- Brugada syndrome
- CPVT (catecholaminergic polymorphic ventricular tachycardia)

In addition to these inherited disorders, a number of less common acquired disorders have independent Guideline-based indications for ICDs. Such disorders include, but are not limited to, amyloidosis, sarcoidosis, cardiac hemochromatosis, and certain forms of myocarditis. When Guideline-based primary prevention indications are identified in patients with these disorders, the 30/40 and/or 90 day waiting periods are not required.

9. Cardiac Resynchronization Therapy

Please refer to Category 2(b) above.

III. DOJ Category with Enforcement—Previously Qualified

An implant in this category is one in which the patient previously qualified for the ICD (pursuant to medical guidelines and Medicare payment rules) but was not implanted with an ICD for whatever reason. This patient subsequently suffered a MI and/or underwent a revascularization, at which time an ICD was implanted based upon the preexisting qualification. An ICD was then implanted within the 30/40 and/or 90 day prohibited time frames.

The patient's clinical record supports that the patient met all of the clinical criteria for the ICD for primary prevention prior to an intervening index event (MI or CABG/PTCA).

This category should only be used if no other DOJ category applies, as there are damages plus a multiplier, to be determined,[4] associated with this category that are not associated with the other above DOJ categories.

Documentation Requirements: There should be documentation stating whether the cardiomyopathy was ischemic or non-ischemic and that there has been "guideline based" medical therapy of generally 3 months. If the patient has ischemic cardiomyopathy, a prior MI must be documented. The patient's LVEF must not exceed 35% (measured at or near the end of the prohibited time frames) prior to the intervening event. The reviewer should reference the NCD for specific documentation points for each of the NCD Indications 3-9.

Documentation to support this category cannot simply be a statement of "long-standing cardiomyopathy." Documentation must include test results preceding the intervening index event. The documentation which supports prior eligibility for the ICD will often be found in the physician's office records or from prior admissions. LVEFs may not be relied upon for this category if the measurement was taken within 30 days after a prior myocardial infarction or revascularization.

[4] See footnotes 1 and 2.

IV. Coding Errors (Without Repeating Patterns)

If a claim does not fit within the NCD or any DOJ category solely because of one of the following coding errors, it should be placed in a "coding error" category. The difference in payment should be calculated, as there are damages plus a multiplier, to be determined,[5] associated with these claims, except as noted below.

A. No MI (the MI was coded in error and there is a difference in the payment)

The medical record documentation supports that the coded MI did not occur. In these cases, there is no documentation in the medical record that an acute MI occurred and the coding of the MI was in error.

Documentation Guidelines: The medical record does not include physician documentation of an acute MI. Alternatively, there may be documentation of an acute MI which is later refuted in the record. If the MI was coded appropriately despite the fact that there was no true MI or if there is no difference in the payment when the MI is taken out, it should be placed in the No MI "category". If it was coded in error and there is a difference in the payment, it should be placed in the coding error category and the difference in payment should be calculated.

B. ICD not implanted (coding error)

A coding error where an ICD was coded but the patient actually had a permanent pacemaker—or no device—placed during the admission in question.

Documentation Guidelines: The medical record documentation in the operative report, procedure log and implant log states that a permanent pacemaker, or no device, was implanted, not an ICD.

C. CABG/PTCA not performed (the CABG/PTCA was coded in error and there is a difference in the payment)

There is no confirmation of the CABG/PTCA in the medical record.

Documentation Guidelines: The medical record supports that the CABG/PTCA was aborted or did not occur. Documentation will not support a CABG/PTCA, but the coding summary shows one of these procedures.

Damages are not applicable where a procedure may not have been completed or was properly coded, such as an aborted PTCA, or an angioplasty/venoplasty for non-revascularization purposes.

[5] See footnotes 1 and 2.

V. ICD implants not covered by the NCD or a DOJ Category, but some justification claimed.

There are damages plus a multiplier, to be determined, [6] associated with these claims.

Examples of these claims may include instances in which:

a) the facility asserts that the MI which preceded the ICD implant was "inconsequential" and treatment is unlikely to result in an improved heart function;

b) the facility asserts that the revascularization which preceded the ICD implant was "incidental" and unlikely to result in an improved heart function;

c) the ICD would have met the criteria of the NCD or a DOJ Category as set forth above, except that there was insufficient documentation as defined above; or

d) a case does not fall within I-IV above, but the facility asserts there is a compelling justification for the implant.

VI. ICD implants which were not medically indicated.

There are damages plus a multiplier, to be determined,[7] associated with these claims.

[6] See footnotes 1 and 2.

[7] See footnotes 1 and 2.

VII. Miscellaneous

1. Any claims for which Medicare did not pay for an ICD should be placed in a "no payment category". Documents explaining a non-payment or partial denial should be provided.

2. Any claim which is part of a Clinical Trial ICD should be placed in a "clinical trial" category. The patient must be part of an IRB-approved clinical trial for ICD-related research or an investigational device exemption (IDE). If the clinical trial is not for an ICD, the clinical trial category is not appropriate. A post market study, which is not a true clinical trial, does not meet this standard. Documents must include the clinical trial consent form or other similar documentation from the patient's record.

3. Although the claims list provided included claims beginning in January of 2002, only claims beginning October 1, 2003 should be reviewed. Claims submitted before this date will be reviewed only in rare circumstances.