December 20, 2017

Ms. Tamara Syrek-Jensen
Director, Coverage & Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: National Coverage Analysis (NCA) for Implantable Cardioverter Defibrillators (CAG-00157R4)

Dear Ms. Syrek-Jensen:

The Heart Rhythm Society (HRS) and the American College of Cardiology (ACC) are the non-profit professional Societies representing most of the practicing electrophysiologists in the United States. The discipline of electrophysiology has undergone significant change in recent years, crossing clinical frontiers in the treatment of sudden cardiac death. HRS and ACC are committed to ensuring access to evidence-based patient care.

HRS and ACC appreciate the opportunity to submit joint comments on the Centers for Medicare and Medicaid Services' (CMS) request for comments on the proposed national coverage determination (NCD) for implantable cardioverter defibrillators (CAG-00157R4). This comment letter represents the two Societies' consensus on recommendations to the Agency to update the policy in a manner that reflects current, evidence-based medicine.

Shared Decision Making (SDM) Interaction Criteria

The Societies are providing comments on CMS's changes requiring a patient SDM encounter prior to ICD implantation for patients who qualify for a primary prevention ICD. We support the Agency's efforts to facilitate patients' understanding of their individual risk of sudden cardiac death and the potential benefits and risks of receiving of an ICD.

The Societies recommend that CMS strongly consider the following when determining mechanisms to promote shared decision making for patients who qualify for a primary prevention ICD:

- Shared decision making is inherent in a referral to an electrophysiologist for an evaluation for a primary prevention ICD. For the most part, a primary prevention ICD patient is a patient referred by another physician to an electrophysiologist.
- The principle of shared decision making has long been an integral component of patient care in electrophysiology programs across the country. During an evaluation for an ICD, the physician and the patient discuss the scientific data regarding benefits, risks and indications of a primary prevention ICD implant as it pertains to his or her individual health goals, preferences and values. This well-established workflow, predicated on evidence-based medicine, occurs in a similar fashion to the informed consent discussion and is documented in the medial record by the implanting physician.
- Requiring an additional and separate SDM encounter with another clinician would be redundant to the current work flow and could delay potentially lifesaving ICD treatment while the additional SDM is being arranged.
- Validated SDM tools employed by the arrhythmia care team will continue to enhance and support quality and patient satisfaction. The profession has developed decision aids in a number of areas, including rhythm management. However, the effectiveness of implementing SDM tools in this patient population is only now being evaluated in a multicenter randomized clinical trial.[1]

For these reasons, the Societies view a requirement for a formal SDM encounter between the patient and an independent clinician to be unnecessary. If CMS determines that the SDM encounter is a requirement of coverage, the Societies provide the following recommendations to maximize the benefits of SDM for patients who are presenting for evaluation and consideration of a primary prevention ICD implant.

> For these patients, a formal shared decision making encounter must occur between the patient and ~~an independent~~ the implanting physician (as defined in Section 1861(r)(1)), or another physician, or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) ~~using and evidence-based decision tool on ICDs~~ with delegated responsibility as a member of the electrophysiology team to provide the patient with evidence-based information on the risks and benefits prior to initial ICD implantation. This process may be enhanced by using evidence-based decision tools as they are developed and validated.

Personal History

The Societies recommend that CMS clarify the intent of the term "personal history" used throughout the policy. This term likely will be unfamiliar to the clinical community and could inadvertently cause confusion in decision making and documentation in the medical record and ultimately to patient care. It seems CMS simply means "medical history." Regardless, there are several instances in the draft NCD where additional information would be helpful. In some instances, the phrase "personal history of cardiac arrest" is used, while in others the type of "personal history" is not defined.

Clinical Indications

The Societies seek clarification or modification to the following clinical indications:

Syncope Presumed to be caused by Ventricular Fibrillation (VT) Or Ventricular Tachycardia (VF)

One of the Societies' recommendations for coverage during the initial comment period in June was to include a waiting period exception for "patients with syncope thought to be due to VT or VF." This recommendation draws on guideline recommendations and supporting evidence regarding evaluation of patients with documented or suspected arrhythmias to diagnose VT or VF in Section 4 of the 2017 guideline. Diagnosis can be made through: a history and physical exam that provides information about medication regimen, coronary artery disease, valve disease, congenital heart disease, or other causes of cardiomyopathy, a 12-lead ECG, exercise treadmill testing, ambulatory electrocardiographic monitoring, implanted cardiac monitors, echocardiography, MRI, CT, electrophysiological study, or angiography.

The Societies seek confirmation that for patients who present with syncope in the setting of an ischemic cardiomyopathy, non-ischemic cardiomyopathy or congenital heart disease, VT or VF can be diagnosed using any of the tests/methods discussed in the guideline to diagnose the likely mechanism of syncope as VT or VF. Our interpretation of the indications covered in Section B.1. of the draft NCD would allow each of those options to document VT or VF. If that is not the case, the Societies recommend that the following language is added to section B.1.

<u>A documented episode of syncope in the setting of structural heart disease and VF or VT.</u>

Waiting Period For Ischemic Cardiomyopathy Changed From 40 Days to 3 Months

The draft policy extends the waiting period from 40 days to 3 months for patients with newly diagnosed ischemic cardiomyopathy beginning guideline-directed medical therapy who do not undergo revascularization. This indication does not align with the clinical trial data and the *2017 ACC/HRS Guidelines for Management of Patients with Ventricular Arrhythmias and Prevention of Sudden Cardiac Death.*[2,3,4] The NCD should be aligned with the following primary prevention indications for ICD implant that are Class I recommendations and have level of evidence A:

- In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days post-revascularization, and with NYHA class II or III HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected. (Level 1 Recommendation, Level of Evidence A, Guideline Recommendation 7.1.2)
- In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days post-revascularization, and with NYHA class I HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected. (Level 1 Recommendation, Level of Evidence A, Guideline Recommendation 7.1.2)

As such, we recommend the indications for severe ischemic and/or non-ischemic dilated cardiomyopathy, NYHA Class II or III heart failure patients with LVEF less than or equal to 35% in covered indication B.3. be separated as follows:

B.3. Patients who have severe ~~ischemic and/or~~ non-ischemic dilated cardiomyopathy but no prior personal history of cardiac arrest, NYHA Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%, been on optimal medical therapy for at least 3 months. Additionally, patients must not have:

- Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
- Had a MI within the past 40 days; or
- Clinical symptoms and findings that would make them a candidate for coronary revascularization.

<u>B.4.</u> Patients who have severe ischemic-dilated cardiomyopathy but no prior personal history of cardiac arrest, NYHA Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%~~, been on optimal medical therapy for at least 3 months~~. Additionally, patients must not have:

- Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
- Had a MI within the past 40 days; or
- Clinical symptoms and findings that would make them a candidate for coronary revascularization.

Class IV heart failure patients awaiting transplant

To further clarify the criteria for patients with Class IV heart failure awaiting transplant, the Societies recommend that the following language is added to section B.3.

- Patients who qualify for ICD under criterion #3 but have NYHA Class IV heart failure and are awaiting heart transplantation.[5-7]

Exception to waiting period for primary prevention ICDs: Cardiac Pacemakers:

To further clarify the criteria for cardiac pacemaker implantation during the primary prevention waiting period, the Societies recommend that the following added language to section C.

Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in this national coverage determination for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated even if this occurs within 40 days post MI or if revascularization occurred within in the past 3 months.

Data Collection

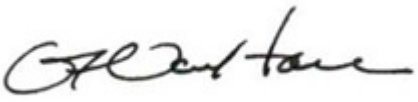
In the 2005 coverage policy, CMS outlined the ten hypotheses necessary to determine that the ICD is reasonable and necessary. Since 2005, the National Cardiovascular Data Registry (NCDR) ICD Registry has collected data to address these ten hypotheses and eight related studies. With these hypotheses addressed, the remaining questions can be addressed by randomized clinical trials and enhanced mechanisms to evaluate device safety and effectiveness.

We appreciate that CMS recognizes the contributions of the ICD Registry and "encourages the continuation and improvement of voluntary registry participation for the purposes of quality improvement, safety, and appropriate use verification." Voluntary registry participation can continue to create value for future patients, clinicians, and facilities as a mechanism of quality improvement, safety, and appropriate use verification. Furthermore, the registry model will remain critical as an essential tool for real world evidence data collection for programs like the National Evaluation System for Health Technology (NEST), new EP devices, and new iterations of current technologies to support evaluation of device safety and effectiveness.

Ongoing collaboration and coordination among CMS, the Food and Drug Administration, the National Institutes of Health, the Agency for Healthcare Quality and Research, and other federal agencies presents an opportunity to ensure funding and timely completion of well-designed studies to answer outstanding questions. The Societies support the coverage with evidence development paradigm to expedite earlier access to innovative technologies that are likely to show benefit for the Medicare population where there is incomplete evidence.

We appreciate the Agency's action to update the coverage policy in a manner that reflects current, evidence-based medicine and clinical practice. If you have questions about the Societies' recommendations, please contact Laura Blum at lblum@hrsonline.org or James Vavricek at jvavricek@acc.org.

Sincerely,



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Citations

1. Matlock D, A Multicenter Trial of a Shared Decision Support Interventiona for Patients Offered Implantable Cardioverter-Defibrillators: DECIDE - ICD Trial. NIH RePORTER - NIH Research Portfolio Online Reporting Tools Expenditures and Results. 2017; https://projectreporter.nih.gov/project_info_description.cfm?aid=9282816&icde=37324464.
2. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society [published online ahead of print October 30, 2017]. Circulation. doi: 10.1161/CIR.0000000000000548. Circulation. doi. 2017;10.
3. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. New England Journal of Medicine. 2002;346(12):877-883.
4. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter–defibrillator for congestive heart failure. New England Journal of Medicine. 2005;352(3):225-237.
5. Fröhlich GM, Holzmeister J, Hübler M, et al. Prophylactic implantable cardioverter defibrillator treatment in patients with end-stage heart failure awaiting heart transplantation. Heart. 2013;99(16):1158-1165.
6. Sandner SE, Wieselthaler G, Zuckermann A, et al. Survival benefit of the implantable cardioverter-defibrillator in patients on the waiting list for cardiac transplantation. Circulation. 2001;104(suppl 1):I-171.
7. Vakil K, Duval S, Cogswell R, et al. Impact of implantable cardioverter-defibrillators on waitlist mortality among patients awaiting heart transplantation: an UNOS/OPTN analysis. JACC: Clinical Electrophysiology. 2016:253.