

## Summary of CMS' Decision Memo for Implantable Cardioverter Defibrillators (ICDs)

On February 15, 2018, the Centers for Medicare and Medicaid Services (CMS) released Medicare's National Coverage Determination (NCD) for Implantable Cardioverter Defibrillators (ICDs). Below is a summary of the changes.

### CMS HIGH-LEVEL CHANGES TO ICD NCD

- Clarified patient indications and primary prevention patients remain covered
- Added in shared decision making for certain patients
- Removed the registry requirement
- Removed the waiting period for certain patients to get their devices

### SUMMARY OF ICD NCD UPDATES

CMS made changes to three areas of the NCD: patient criteria, waiting periods and the registry requirement. They are highlighted below:

#### Patient Criteria

- A. Added cardiac magnetic resonance imaging (MRI) to the list of diagnostic imaging studies that can evaluate left ventricular ejection fraction (LVEF);
- B. Required patients who have severe non-ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation to have been on optimal medical therapy (OMT) for at least 3 months;
- C. Required a patient shared decision making (SDM) interaction prior to ICD implantation for all indicated patients except:
  1. Patients with a personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation
  2. Patients with an existing ICD needing a replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction;
- D. Removed the Class IV heart failure requirement for cardiac resynchronization therapy (CRT).

#### Exceptions to Waiting Periods

- A. Added an exception for patients meeting CMS coverage requirements for cardiac pacemakers, and who meet the criteria for an ICD;
- B. Added an exception for patients with an existing ICD and qualifying replacement.

## Registry Requirement

- A. Ended the data collection requirement so that clinicians are no longer required to submit data to the NCDR Registry.<sup>1</sup>

Many of the changes serve to clarify patient populations and recognize current clinical practice for ICDs. The shared decision making requirement is one of the few changes that has raised some questions. In the NCD, CMS has described it as “a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.”<sup>2</sup>

CMS’ intent was to facilitate a discussion between the patient and a clinician “in which treatment decisions are based not only on the best available evidence but also on the patients’ health goals, preferences, and values.”<sup>3</sup> In the analysis of the NCD, CMS emphasized:

- “the use of an evidence-based tool [ensures] topics like the patients’ health goals and preferences are covered before ICD implantation.”<sup>4</sup>
- CMS stated that the physician or non-physician professional facilitating the discussion does not need to be “independent.”<sup>5</sup> The implanting physician or their team member are often best able to discuss options such as (but not limited to) the risks and benefits of not implanting an ICD, implantation of a subcutaneous versus transvenous device, programming needs, device placement, diagnostics, battery longevity, and single vs. dual chamber.

To access the full text of the NCD and its analysis, click [here](#)

## COMMENTS / QUESTIONS

If you have questions or would like additional information contact:

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<sup>1</sup> Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4), <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=288&CALId=175&CalName=Removal+of+ICD-9-CM+Code+V76.51%2c+Special+Screening+for+Malignant+Neoplasms+of+Colon%2c++From+the+List+of+Codes+Never+Covered+by+Medicare&ExpandComments=y&CommentPeriod=0&NCDId=110&ncdver=3&ver=11&CoverageSelection=National&Keyword=ICD&KeywordLookUp=Title&KeywordSearchType=And&IsPopup=y&bc=AAAAAAAAQAAA&> (accessed February 23, 2018)  
<sup>2,3,4,5</sup> Ibid.