



## NCD 20.4 Implantable Cardiac Defibrillators (ICDs)

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We revised this Article to add a link to MLN Article [MM12104](#) that tells you about Medicare claims processing system changes for Implantable Cardiac Defibrillators (ICDs) with dates of service on or after February 15, 2018. All other information is unchanged.

### Provider Types Affected

This MLN Matters Article is for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for Implantable Cardiac Defibrillators (ICDs) provided to Medicare beneficiaries.

### Provider Action Needed

SE20006 updates providers on Medicare coverage rules and policies for National Coverage Determination (NCD) 20.4 – Implantable Cardiac Defibrillators (ICDs). SE20006 outlines the coding requirements (including the heart failure codes) and is not more restrictive than the NCD. Please make sure your billing staff knows about these updates.

### Background

The Centers for Medicare & Medicaid Services (CMS) previously issued [MM10865](#) (based on CR 10865), which informed providers that, “effective February 15, 2018, coverage policy is no longer contingent on participation in a trial/study/registry. Therefore, claims with a Date of Service (DOS) on or after February 15, 2018, no longer require any trial-relative coding.”

CMS has received communications with concerns that appear to relate to three specific indications in the NCD for ICDs and this article addresses those indications. Those indications are:

1. Patients with a prior myocardial infarction (MI) and a measured left ventricular ejection fraction (LVEF)  $\leq$  0.30. Patients must not have:
  - New York Heart Association (NYHA) classification IV heart failure; or
  - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
  - Had an MI within the past 40 days; or

- Clinical symptoms and findings that would make them a candidate for coronary revascularization
2. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachycardia (VT) or cardiac arrest due to ventricular fibrillation (VF), and have NYHA Class II or III heart failure, LVEF  $\leq$  35 percent. Additionally, patients must not have:
    - Had a CABG or PCI with angioplasty and/or stenting, within the past 3 months; or
    - Had an MI within the past 40 days; or
    - Clinical symptoms and findings that would make them a candidate for coronary revascularization
  3. Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of cardiac arrest or sustained VT, NYHA Class II or III heart failure, LVEF  $\leq$  35 percent, and been on optimal medical therapy for at least 3 months. Additionally, patients must not have:
    - Had a CABG or PCI with angioplasty and/or stenting, within the past 3 months; or
    - Had an MI within the past 40 days; or
    - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

### Heart Failure ICD-10 Codes Requirement

The current requirements for reporting heart failure codes (ICD-10 diagnosis codes I50.21, I50.22, I50.23, I50.41, I50.42, and I50.43) for patients with ischemic or non-ischemic cardiomyopathy are based on NCD language, which specifically adds this requirement. While CMS agrees that the NYHA classification of heart failure is a functional classification and may not directly map to LVEF, the fact remains that for the cardiomyopathies so specified, the NCD does additionally require heart failure to be present, even if adequately treated and compensated, hence the requirement for these codes to appear on the claim. The inclusion of language qualifying the magnitude of the ejection fraction is to distinguish between the clinical entities of heart failure associated with preserved or high ejection fractions from that of heart failure associated with low ejection fractions. Clinical evidence supports coverage of the latter.

CMS believes that perhaps some have misinterpreted correct coding principles with respect to the use of these codes. CMS agrees that patients do not have to have “active heart failure” to qualify for an Automatic Implantable Cardioverter Defibrillator (AICD) but they also do not have to have “active heart failure” in order to append one of these codes. Patients with a cardiomyopathy and a reduced ejection fraction, who experience an episode of active or acute heart failure, and who are hospitalized, treated conventionally with diuretics, afterload reduction, etc., who then improve to the point they can be discharged on a medical regimen still have heart failure. They may be “compensated” but they are still considered a heart failure patient and as such, the use of the appropriate heart failure code is consistent with correct coding principles. Indeed, an analysis of the claim experience in this regard is consistent with this concept. In summary, if left ventricular function remains impaired and they have had to undergo treatment

at some time in the past for clinical signs and symptoms of heart failure, but are now compensated with therapy, they may still be appropriately denoted with a heart failure code. Should left ventricular impairment be transient, with return to a normal ejection fraction, this dynamic would not apply and coverage criteria would not be met.

CMS does not agree with the suggestion that the unspecified heart failure code (I50.9) should be added to the covered codes for this NCD because one cannot determine what type of heart failure may be, or may have been, present. Consistent with the current standard of care, most patients, ill enough to engender consideration of the placement of an AICD, have had a diagnostic evaluation sufficient to evaluate wall motion, ejection fraction, cardiac chamber size and thickness, etc. We believe the information from the common diagnostic studies they typically undergo is sufficient to classify them with the current specific codes listed in the NCD.

For post MI patients, the heart failure diagnosis requirement is also supported by the American College of Cardiology, the American Heart Association and the Heart Rhythm Society guidelines (See Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: Executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. 2017.). Specifically, those recommendations are noted below:

- In patients with LVEF of 35 percent 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 heart failure despite guideline-directed medical treatment (GDMT), an ICD is recommended if meaningful survival of greater than 1 year is expected (1, 2) (LOE: A).
- In patients with LVEF of 30 percent 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 heart failure despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected (2, 3) (LOE: A).

Finally, the article which outlines the coding requirements (including the heart failure codes) is not more restrictive than the NCD. CMS agrees the NCD does not specifically use the terms encompassed by the heart failure code descriptors. Correct coding principles require a "menu" of codes be available such that providers can match those codes to the individual characteristics of each patient who may meet the overall coverage requirements in the NCD. Those requirements are simply heart failure with low ejection fraction. It is incumbent upon the provider to select the proper code(s). We believe the listed covered codes encompass the various clinical scenarios that occur for patients who meet the NCD coverage requirements and are provided, not to write additional parameters into the NCD, but to ensure there is an appropriate code for the covered indications.

## More Information

The official instruction issued to your MAC regarding CR 10865 is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R213NCD.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

## Document History

Date of Change	Description
August 20, 2021	We revised this Article to add a link to MLN Article <a href="#">MM12104</a> that tells you about Medicare claims processing system changes for ICDs with dates of service on or after February 15, 2018. All other information is unchanged.
March 3, 2020	Initial article released.

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