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NCD 20.4 Implantable Cardiac Defibrillators (ICDs)

MLN Matters Number: MM10865 Revised
Related Change Request (CR) Number: 10865
Related CR Release Date: February 15, 2019
Effective Date: February 15, 2018
Related CR Transmittal Number: R213NCD
Implementation Date: March 26, 2019 - MAC local edits

Note: We revised this article on February 26, 2019, to reflect a revised CR10865 issued on February 15. CMS revised the CR to change the implementation date to March 26, 2019, and we revised the article accordingly. Also, we revised the CR release date, transmittal number, and the Web address of the CR. All other information is unchanged.

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

CR 10865 and the Medicare National Coverage Determinations (NCD) Manual Transmittal reflects the Centers for Medicare & Medicaid Services (CMS) final decision dated February 15, 2018, regarding the reconsideration of NCD 20.4, Implantable Defibrillators (ICDs). Make sure your billing staffs are aware of this decision. 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 an after February 15, 2018, no longer require any trial-related coding.

BACKGROUND

An ICD is an electronic device designed to diagnose and treat life-threatening Ventricular Tachyarrhythmias (VTs). The device consists of a pulse generator and electrodes for sensing and defibrillating. This therapy has been shown in trials to improve survival and reduce sudden cardiac death in patients with certain clinical characteristics.

Section 20.4 of the Medicare NCD Manual establishes conditions of coverage for ICDs. In 1986, CMS first issued an NCD providing limited coverage of ICDs and the policy has been expanded over the years. CMS last reconsidered this NCD in 2005. Effective for claims with dates of service on or after February 15, 2018, CMS will cover ICDs for the following patient indications:

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1. Patients with a personal history of sustained VT or cardiac arrest due to Ventricular Fibrillation (VF). Patients must have demonstrated:
    - An episode of sustained 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; or
    - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.
2. Patients with a prior MI and a measured left ventricular ejection fraction (LVEF) ≤ 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.
3. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have New York Heart Association (NYHA) Class II or III heart failure, LVEF ≤ 35%. 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.
4. 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 ≤ 35%, 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.
5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.
6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

For these patients identified in items 2 through 5 above, a formal shared decision-making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of

the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision-making encounter may occur at a separate visit.

For each of the 6 covered indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (for example, not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. Patients must not have:
    - Significant, irreversible brain damage; or,
    - Any disease, other than cardiac disease (for example, cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or,
    - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that 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:

- Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in NCD 20.4 for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;
- Replacement of ICDs: Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, ERI, or device/lead malfunction.

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, as with cardiac resynchronization therapy, when used as a bridge-to-transplant to prolong survival until a donor becomes available, MACs determine coverage of ICDs.

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B investigational device exemption (IDE) trials per regulation at 42 CFR 405.201.

ADDITIONAL INFORMATION

The official instruction, CR 10865, issued to your MAC regarding this change 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
February 26, 2019	We revised this article to reflect a revised CR10865 issued on February 15. CMS revised the CR to change the implementation date to March 26, 2019, and we revised the article accordingly. Also, we revised the CR release date, transmittal number, and the Web address of the CR. All other information is unchanged.
December 17, 2018	The article was revised to reflect a revised CR10865 issued on December 13. In the article, two sentences are added at the end of the Provider Action Needed section to emphasize that this coverage policy no longer requires trial-related coding on claims for dates of service on or after February 15, 2018. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information is unchanged.
December 3, 2018	This article was revised on December 3, 2018, to correct the implementation date in the banner above. That date should be February 26, 2019.
November 29, 2018	Initial article released.