



Claims Processing Instructions for National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)

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We revised this Article to add a link to MLN Article [SE20006](#) that updates Medicare coverage rules and policies for National Coverage Determination (NCD) 20.4 – Implantable Cardiac Defibrillators (ICDs). All other information is unchanged.

Provider Types Affected

This MLN Matters Article is for physicians, hospitals, and providers billing Medicare Administrative Contractors (MACs) for Implantable Cardiac Defibrillator (ICD) services they provide to Medicare patients.

Provider Action Needed

This article tells you about Medicare claims processing system changes for ICDs with dates of service on or after February 15, 2018. Make sure your billing staff is aware of these instructions.

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. Trials show this therapy improves survival and reduces sudden cardiac death in patients with certain clinical characteristics.

[Section 20.4](#) of the Medicare National Coverage Determinations (NCD) Manual establishes conditions of coverage for ICDs. In 1986, CMS first issued an NCD providing limited coverage of ICDs and we expanded the policy over the years. CMS last reconsidered this NCD in 2005.

CR 12104 provides that, effective for claims with dates of service on or after February 15, 2018, CMS will cover ICDs for the following patient indications: (Please see [Section 20.4](#) of the NCD Manual for the full list of coverage criteria.)

1. Patients with a personal history of sustained VT or cardiac arrest due to Ventricular Fibrillation (VF)
2. Patients with a prior Myocardial Infarction (MI) and a measured Left Ventricular Ejection Fraction (LVEF) ≤ 0.30

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 \leq 35%
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 \leq 35%, and been on optimal medical therapy for at least 3 months
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 indications 2-5 above, a formal shared decision making encounter must occur between the patient and a physician (as defined in [Section 1861\(r\)\(1\)](#) of the Social Security Act (the Act)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to ICD implantation.

Note: This shared decision-making encounter may occur at a separate visit.

You should be aware of these exceptions to waiting periods for patients that 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 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 who are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list, and are awaiting a donor heart, coverage of ICDs, as with cardiac resynchronization therapy, as a bridge-to-transplant to prolong survival until a donor becomes available, is determined by your MAC.

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B Investigational Device Exemption (IDE) trials ([42 CFR 405.201](#)).

Also, you should be aware that, effective February 15, 2018, coverage policy is no longer contingent on participation in a trial/study/registry. Therefore, claims with dates of service on and after February 15, 2018, no longer require trial-related coding unless they are associated with a Category B IDE trial, in which case ICD-10 Z00.6 must be appended to the claim.

Coding Requirements for ICDs

See Publication 100-04, Medicare Claims Processing Manual, [Chapter 32, Section 270](#), for specific claims processing information for ICDs, as well as the business requirements included in CR 12104, [Transmittal 10635CP](#).

You should also be aware that MACs will not search their files for claims for ICD services with dates of service between February 15, 2018, and the implementation date of CR 12104 unless you bring such claims to their attention.

More Information

The official instruction, CR 12104, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10635CP.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 18, 2021	We revised this Article to add a link to MLN Article SE20006 that updates Medicare coverage rules and policies for NCD 20.4 – Implantable Cardiac Defibrillators (ICDs). All other information is unchanged.
March 24, 2021	Initial article released.

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