

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 211	Date: December 13, 2018
	Change Request 10865

Transmittal 209, dated November 21, 2018, is being rescinded and replaced by Transmittal 211, dated, December 13, 2018, to add a clarifying note to the policy section of the Business Requirements document that was inadvertently left out. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)

I. SUMMARY OF CHANGES: This Change Request (CR) and Publication (Pub.) 100-03 Medicare NCD Manual reflects the Agency's final decision dated February 15, 2018, regarding the reconsideration of NCD 20.4, Implantable Cardiac Defibrillators. A subsequent CR will be released at a later date that contains a Pub.100-04 Claims Processing Manual update with accompanying instructions. Until that time, the Medicare Administrative Contractors (MACs) shall be responsible for implementing NCD 20.4.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (CFR) section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: February 15, 2018

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: February 26, 2019 - of this CR - MAC local edits

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revise information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/20.4/Implantable Cardioverter Defibrillators (ICD)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to

be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

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SUBJECT: National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)

EFFECTIVE DATE: February 15, 2018

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I. GENERAL INFORMATION

A. Background: An Implantable Cardiac Defibrillator (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 National Coverage Determinations (NCD) Manual establishes conditions of coverage for ICDs. In 1986, the Centers for Medicare & Medicaid Services (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.

B. Policy: 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 additional 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 three (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

Number	Requirement	Responsibility							
		A/B MAC		H H H	D M E M A C	Shared-System Maintainers			Other
		A	B			F I S S	M C S	V M S	
	NOTE: CMS shall schedule the calls at a later date.								
10865.2.2	Contractors shall be responsible for taking meeting notes on a rotating basis and submit notes into ECHIMP, under the Post Issued tab, Analysis Call Documents sub-tab, within 3 business days of meeting. Contractors shall provide appropriate points-of-contact for staffing the meetings and send the contact information within 7 business days of the date of issuance of this CR to:David.Dolan@cms.hhs.gov	X	X						
10865.3	Contractors shall provide consensus recommendations to CMS in a final report uploaded into ECHIMP, under the Post Issued tab, Analysis Call Documents sub-tab, no later than 30 business days following the final meeting.	X	X						
10865.4	A/B MACs shall implement local edits in each respective jurisdiction until such time as CMS may determine shared edits to be appropriate, which will be relayed via a subsequent CR.	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC		H H H	D M E M A C	C E D I	
		A	B				
10865.5	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual Chapter 1, Part 1(Sections 10-80.12)

Table of Contents
(Rev.211, Issued: 12-13-18)

20.4 – Implantable Cardioverter Defibrillators (ICDs)

20.4 – Implantable Cardioverter Defibrillators (ICDs)
(Rev. 211, Issued: 12-13-18 Effective: 02-15-18, Implementation: 02-26-19)

A. General

An ICD is an electronic device designed to diagnose and treat life-threatening ventricular tachyarrhythmias.

B. Nationally Covered Indications

Effective for services performed on or after February 15, 2018, CMS has determined that the evidence is sufficient to conclude that the use of ICDs, (also referred to as defibrillators) is reasonable and necessary:

- 1. Patients with a personal history of sustained Ventricular Tachyarrhythmia (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) \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 three (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.*

For these patients identified in B2, 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 initial ICD implantation. The shared decision making encounter may occur at a separate visit.

- 3. Patients who have severe, ischemic, dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have NYHA Class II or III heart failure, LVEF \leq 35%. Additionally, patients must not have:*
 - Had a CABG, or PCI with angioplasty and/or stenting, within the past three (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.*

For these patients identified in B3, 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 §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.

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%, been on optimal medical therapy for at least three (3) months. Additionally, patients must not have:*
 - *Had a CABG or PCI with angioplasty and/or stenting, within the past three (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.*

For these patients identified in B4, 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 §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.

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).*

For these patients identified in B5, 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 §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.

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

1. *Patients must be clinically stable (e.g., 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 (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than one (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 three (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 this national coverage determination 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.

C. Nationally Non-Covered Indications

N/A

D. Other

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list 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 the local Medicare Administrative Contractors (MACs).

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).

(This NCD last reviewed February 2018.)