UnitedHealthcare® Medicare Advantage Policy Guideline

IMPLANTABLE AUTOMATIC DEFIBRILLATORS (NCD 20.4)

Guideline Number: MPG151.06

Table of Contents

<table>
<thead>
<tr>
<th>TERMS AND CONDITIONS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PURPOSE</td>
<td>1</td>
</tr>
<tr>
<td>POLICY SUMMARY</td>
<td>2</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>3</td>
</tr>
<tr>
<td>QUESTIONS AND ANSWERS</td>
<td>5</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>5</td>
</tr>
<tr>
<td>GUIDELINE HISTORY/REVISION INFORMATION</td>
<td>6</td>
</tr>
</tbody>
</table>

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT® **), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

**CPT® is a registered trademark of the American Medical Association.

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.
UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**POLICY SUMMARY**

**Overview**
An ICD (also referred to as defibrillators) is an electronic device designed to diagnose and treat life-threatening ventricular tachyarrhythmias.

**Guidelines**

**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 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) < 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 < 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 < 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:
- Patients must be clinically stable (e.g., not in shock, from any etiology);
- LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac Magnetic Resonance Imaging (MRI), or catheter angiography;
- 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.

Nationally Non-Covered Indications
Non-Applicable

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).

CMS last review February 2018

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>33230</td>
<td>Insertion of pacing cardioverter-defibrillator pulse generator only; with existing dual leads</td>
</tr>
<tr>
<td>33231</td>
<td>Insertion of pacing cardioverter-defibrillator pulse generator only; with existing multiple leads</td>
</tr>
<tr>
<td>33240</td>
<td>Insertion of pacing cardioverter-defibrillator pulse generator only; with existing single lead</td>
</tr>
<tr>
<td>33241</td>
<td>Removal of pacing cardioverter-defibrillator pulse generator only</td>
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<tr>
<td>33243</td>
<td>Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy</td>
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<tr>
<td>CPT Code</td>
<td>Description</td>
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<tr>
<td>33244</td>
<td>Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by transvenous extraction</td>
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<tr>
<td>33249</td>
<td>Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber</td>
</tr>
<tr>
<td>33262</td>
<td>Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system</td>
</tr>
<tr>
<td>33263</td>
<td>Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system</td>
</tr>
<tr>
<td>33264</td>
<td>Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system</td>
</tr>
<tr>
<td>33270</td>
<td>Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed</td>
</tr>
<tr>
<td>33271</td>
<td>Insertion of subcutaneous implantable defibrillator electrode</td>
</tr>
<tr>
<td>33272</td>
<td>Removal of subcutaneous implantable defibrillator electrode</td>
</tr>
<tr>
<td>33273</td>
<td>Repositioning of previously implanted subcutaneous implantable defibrillator electrode</td>
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<tr>
<td>93260</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system</td>
</tr>
<tr>
<td>93261</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system</td>
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<tr>
<td>93282</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93283</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93284</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93289</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements</td>
</tr>
<tr>
<td>93295</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93644</td>
<td>Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)</td>
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*CPT® is a registered trademark of the American Medical Association*
ICD-10 Procedure Code | Description
--- | ---
02HK0KZ | Insertion of Defibrillator Lead into Right Ventricle, Open Approach
02HK3KZ | Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Approach
02HK4KZ | Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Endoscopic Approach
02HL0KZ | Insertion of Defibrillator Lead into Left Ventricle, Open Approach
02HL3KZ | Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Approach
02HL4KZ | Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Endoscopic Approach
02HL5KZ | Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Approach
0JH608Z | Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach
0JH638Z | Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
0JH808Z | Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach
0JH838Z | Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

ICD-10 Diagnosis Codes

QUESTIONS AND ANSWERS

1 Q: What happened to the ICD-10 codes for coronary artery disease (CAD)?
   A: CAD was removed by CMS as a covered indication.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 20.4 Implantable Automatic Defibrillators

CMS Local Coverage Determinations (LCDs)

CMS Articles

CMS Benefit Policy Manual
Chapter 14: § 20 FDA Approval Investigational Device Exemptions (IDE) Studies

CMS Claims Processing Manual
Chapter 32; § 270 Claims Processing for Implantable Automatic Defibrillators, § 270.1 Coding Requirements for Implantable Automatic Defibrillators, § 270.2 Billing Requirements for Patients Enrolled in a Data Collection System
CMS Transmittals
Transmittal 211, Change Request 10865, Dated 12/13/2018 (National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs))

MLN Matters
Article MM7296, MRI in Medicare Beneficiaries with Implanted Permanent Pacemakers (PMs) or Implantable Cardioverter Defibrillators (ICDs)

Others
CMS Implantable Cardioverter Defibrillators (ICD) Registry
CMS Investigational Device Exemption Approved Studies

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>02/13/2019</td>
<td>• Annual review</td>
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