IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

Transvenous/Subcutaneous ICDs

Medicare National Coverage Determination (NCD) 20.4 Checklist

NCD 20.4	**Patient Name:**	**MR#**

Effective Date: For services performed on or after 02/15/2018

An implantable cardioverter defibrillator is a battery-driven electronic device designed to detect and treat life-threatening ventricular tachyarrhythmias. It consists of a pulse generator and electrodes for sensing and defibrillating. The device monitors the heart's electrical activity, detects and tries to terminate the onset of life-threatening tachyarrhythmias, first by small electrical stimuli and then with shock therapy. The "shock" temporarily stops all cardiac electrical signals and allows the heart to "reset" itself back to a normal sinus rhythm. There are two general categories of defibrillators: transvenous implantable cardioverter-defibrillators (ICD) and subcutaneous implantable defibrillators (S-ICD).

GENERAL REQUIREMENTS

□ Patients must be clinically stable (e.g., not in shock, from any etiology).

□ Left ventricular ejection fraction (LVEF) must be measured by echocardiography, radionuclide imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography.

□ Patients must not have:

- Significant, irreversible brain damage; or
- Diseases other than cardiac (e.g., cancer, renal/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 coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months, or had a myocardial infarction within the past 40 days:

□ Cardiac Pacemakers: Patients who meet all CMS coverage requirements, and who meet NCD criteria 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, elective replacement indicator (ERI), or device/lead malfunction.

COVERAGE INDICATIONS

A defibrillator IS considered medically reasonable and necessary for ANY of the following 6 indications.

1. Patients with a personal history of sustained ventricular tachyarrhythmia (VT) or cardiac arrest due to ventricular fibrillation.	**2. Patients with a prior myocardial infarction with a measured left ventricular ejection fraction (LVEF) ≤ 0.30 .**	**3. Patients who have severe ischemic dilated cardiomyopathy with a New York Heart Association (NYHA) classification II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 0.35%, with no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation.**	**4. Patients who have severe non-ischemic dilated cardiomyopathy with a New York Heart Association (NYHA) classification II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 0.35%, and optimal medical therapy for at least 3 months, with no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation.**	**5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained ventricular tachycardia or ventricular fibrillation) to include, but not limited to long QT syndrome or hypertrophic cardiomyopathy.** ***Requires a documented formal shared decision making encounter.***	**6. Patients with an existing ICD may receive a replacement for the end of battery life, elective replacement indicator (ERI) , or device/lead malfunction.**
Patients must have demonstrated: ● An episode of sustained ventricular tachyarrhythmia, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction and not due to a transient or reversible cause; or ● An episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause.	Patients must not have: ● New York Heart Association (NYHA) classification IV heart failure; ● Had a coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) with angioplasty and/or stenting within the past 3 months; or ● Had a myocardial infarction within the past 40 days; or ● Clinical symptoms and findings that would make them a candidate for coronary revascularization. ***Requires a documented formal shared decision making encounter.**	Patients must not 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 a myocardial infarction within the past 40 days; or ● Clinical symptoms and findings that would make them a candidate for coronary revascularization. ***Requires a documented formal shared decision making encounter.**	Patients must not 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 a myocardial infarction within the past 40 days; or ● Clinical symptoms and findings that would make them a candidate for coronary revascularization. ***Requires a documented formal shared decision making encounter.***		

Other Indications:

□ For patients that are candidates for heart transplantation on the UNOS transplant list awaiting a donor hear, 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 IDE trials.

DOCUMENTATION REQUIREMENTS

□ ***Formal Shared Decision Making Encounter (2-5) -** A documented formal shared decision making encounter which must occur between the patient and a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool (see the link) on ICDs prior to initial ICD implantation for indications above (2-5). This encounter may occur at a separate visit.	ICD Shared Decision Making Tools

Checklist completed by: **Date:**

Disclaimer: *The content of the checklists were created as an educational tool. Use of these documents are not intended as a replacement for the documentation requirements published in National or Local Coverage Determinations, or the CMS's documentation guidelines, written law or regulations. Medicare policy changes frequently; Providers/Departments are reminded to review current National and Local Coverage Determination and Policy Articles for specific documentation and coding guidelines.*