

EFFECTIVE DATE: 01|01|2015
POLICY LAST UPDATED: 03|03|2015

OVERVIEW

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death. A subcutaneous ICD (S-ICD®) has been developed that does not employ transvenous leads, with the goal of reducing lead-related complications.

Note: This policy applies to the Subcutaneous Implantable Cardioverter Defibrillator only. Implantable Cardioverter Defibrillator (ICD) Insertions (not Subcutaneous) will require prior authorization and will be added to the BCBSRI online prior authorization tool. See the Related Policies section.

MEDICAL CRITERIA

Not Applicable

PRIOR AUTHORIZATION

Prior authorization review is recommended for Commercial products for the removal of a subcutaneous implantable defibrillator electrode.

POLICY STATEMENT

BlueCHiP for Medicare

Subcutaneous implantable automatic defibrillators are medically necessary. Effective June 1, 2015, prior authorization will be required for BlueCHiP for Medicare and is obtained via the online tool for participating providers. See related policies section.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Commercial products

Subcutaneous implantable automatic defibrillators are considered not medically necessary as there is insufficient peer-reviewed literature that demonstrates that the service is effective.

The removal of a subcutaneous implantable defibrillator electrode may be covered when determined to be medically necessary. Prior authorization is recommended for this service.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable "not medically necessary" services/benefits.

BACKGROUND

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death.

Indications for ICD implantation can be broadly subdivided into (1) secondary prevention, ie, their use in patients who have experienced a potentially life-threatening episode of VT (near sudden cardiac death); and (2) primary prevention, ie, their use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or VF.

The standard ICD involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator, which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized.

A totally subcutaneous ICD (S-ICD®) has also been developed. This device does not employ transvenous leads and thus avoids the need for venous access and complications associated with the venous leads. Rather, the S-ICD® uses a subcutaneous electrode that is implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous tissue of the chest wall.

A subcutaneous ICD (S-ICD®) has been developed that does not employ transvenous leads, with the goal of reducing lead-related complications. Evidence from nonrandomized controlled studies report success rates in terminating laboratory-induced VFs that are similar to transvenous ICD. However, there is scant evidence on comparative clinical outcomes of both types of ICD over longer periods of time. Case series report high rates of detection and successful conversion of VT, and inappropriate shock rates that are in the range reported for transvenous ICD. This evidence is not sufficient to determine whether there are small differences in efficacy between the 2 types of devices, which may be clinically important due to the nature to the disorder being treated. Also, the adverse event (AE) rate is uncertain, with variable rates of AEs reported in the available studies. At least 1 RCT is currently underway to compare S-ICD with transvenous ICD. Because of the uncertainties around whether the S-ICD is as effective as transvenous ICD and uncertainties around the AE rates, the use of the S-ICD is considered not medically necessary for Commercial products.

BlueCHiP for Medicare

CMS covers implantable automatic defibrillators based on the the indications found in the National Coverage Determination (NCD) 20.4. This NCD is not specific for subcutaneous implantable cardioverter-defibrillator.

Covered Indications and limitations of coverage from NCD 20.4:

1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause (effective July 1, 1991).
2. Documented sustained ventricular tachyarrhythmia (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 (effective July 1, 1999).
3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy (effective July 1, 1999).

Additional indications effective for services performed on or after October 1, 2003:

4. Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) ≤ 0.35 , and inducible, sustained VT or VF at EP study.
(The MI must have occurred more than 40 days prior to defibrillator insertion.
The EP test must be performed more than 4 weeks after the qualifying MI.)

5. Documented prior MI and a measured LVEF ≤ 0.30 and a QRS duration of >120 milliseconds (the QRS restriction does not apply to services performed on or after January 27, 2005).

Patients must not have:

- a. New York Heart Association (NYHA) classification IV;
- b. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- c. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months;
- d. Had an enzyme positive MI within past month (Effective for services on or after January 27, 2005, patients must not have an acute MI in the past 40 days);
- e. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
- f. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.

Additional indications effective for services performed on or after January 27, 2005:

6. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF $\leq 35\%$;
7. Patients with non-ischemic dilated cardiomyopathy (NIDCM) >9 months, NYHA Class II and III heart failure, and measured LVEF $\leq 35\%$;
8. Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;

All indications must meet the following criteria:

- a. Patients must not have irreversible brain damage from preexisting cerebral disease;
- b. MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;

Indications 3 - 8 (primary prevention of sudden cardiac death) must also meet the following criteria:

- a. Patients must be able to give informed consent;
- b. Patients must not have:
 - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
 - Had a CABG or PTCA within the past 3 months;
 - Had an acute MI within the past 40 days;
 - Clinical symptoms or findings that would make them a candidate for coronary revascularization;
 - Irreversible brain damage from preexisting cerebral disease;
 - Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;
- c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;
- d. The beneficiary receiving the defibrillator implantation for primary prevention is enrolled in either a Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (National Coverage Determination (NCD) Manual §310.1) or a qualifying data collection system including approved clinical trials and registries. Initially, an implantable cardiac defibrillator (ICD) database will be maintained using a

data submission mechanism that is already in use by Medicare participating hospitals to submit data to the Iowa Foundation for Medical Care (IFMC) a Quality Improvement Organization (QIO) contractor for determination of reasonable and necessary and quality improvement. Initial hypothesis and data elements are specified in this decision (Appendix VI) and are the minimum necessary to ensure that the device is reasonable and necessary. Data collection will be completed using the ICDA (ICD Abstraction Tool) and transmitted via QNet (Quality Network Exchange) to the IFMC who will collect and maintain the database. Additional stakeholder-developed data collection systems to augment or replace the initial QNet system, addressing at a minimum the hypotheses specified in this decision, must meet the following basic criteria:

- Written protocol on file;
- Institutional review board review and approval;
- Scientific review and approval by two or more qualified individuals who are not part of the research team;
- Certification that investigators have not been disqualified.

For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

- e. Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the patient's medical record.

9. Patients with NIDCM >3 months, NYHA Class II or III heart failure, and measured LVEF \leq 35%, only if the following additional criteria are also met:

- a. Patients must be able to give informed consent;
- b. Patients must not have:

- Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
- Had a CABG or PTCA within the past 3 months;
- Had an acute MI within the past 40 days;
- Clinical symptoms or findings that would make them a candidate for coronary revascularization;
- Irreversible brain damage from preexisting cerebral disease;
- Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year;

- c. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography;
- d. MIs must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction;²
- e. The beneficiary receiving the defibrillator implantation for this indication is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1), or a prospective data collection system meeting the following basic criteria:

- Written protocol on file;
- Institutional Review Board review and approval;
- Scientific review and approval by two or more qualified individuals who are not part of the research team;
- Certification that investigators have not been disqualified.

For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

f. Providers must be able to justify the medical necessity of devices other than single lead devices. This justification should be available in the patient's medical record.

C. Other Indications

All other indications for implantable automatic defibrillators not currently covered in accordance with this decision will continue to be covered under Category B IDE trials (42 CFR §405.201) and the CMS routine clinical trials policy (NCD §310.1).

Alpert and Thygesen et al., 2000. Criteria for acute, evolving or recent MI.

Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI:

1. Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:

- a. ischemic symptoms;
- b. development of pathologic Q waves on the ECG;
- c. ECG changes indicative of ischemia (ST segment elevation or depression); or
- d. coronary artery intervention (e.g., coronary angioplasty).

2. Pathologic findings of an acute MI.

Criteria for established MI.

Any one of the following criteria satisfies the diagnosis for established MI:

1. Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed.
2. Pathologic findings of a healed or healing MI.

CODING

BlueCHiP for Medicare and Commercial

The following CPT codes effective on January 1, 2015 are covered when medically necessary for BlueCHiP for Medicare and not medically necessary for Commercial products:

33270 33271 33273

The following CPT code effective on January 1, 2015 is covered when medically necessary for BlueCHiP for Medicare and Commercial. Preauthorization is recommended for Commercial products:

33272

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, May 2015

REFERENCES:

1. CMS.gov Centers for Medicare and Medicaid Services; National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4) <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=110&ncdver=3&bc=AgAAgAAAAAAAAAAAA%3d%3d&>
2. CMS.gov Centers for Medicare and Medicaid Services; National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=1&ncdver=2&bc=AgAAgAAAAAAAAAAAA%3d%3d&>
3. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. *Eur Heart J*. Jul 1 2014;35(25):1657-1665. PMID 24670710
4. Gold MR, Weiss R, Theuns DA, et al. Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm*. Aug 2014; 11(8):1352-1358. PMID 24732366
5. Kooiman KM, Knops RE, Olde Nordkamp L, et al Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: Implications for management. *Heart Rhythm*. 2014;11(3):426-434. PMID
6. Groh CA, Sharma S, Pelchovitz DJ, et al. Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm*. Aug 2014; 11(8):1361-1366. PMID 24755323

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