TEXAS - MAC - PART B - TRAILBLAZER

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19297	L26834
19298	L26834
31643	L26834
33240	L26500
33249	L26500
35475	L26737
35476	L26737
36005	L26737
36010	L26737
36215	L26737
36216	L26737
36217	L26737
36470	L26729
36471	L26729
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36810	L26737
36815	L26737
36819	L26737
36821	L26737
37201	L26772
37202	L26778
37205	L28638
37206	L28638
37207	L28638
37208	L28638
47380	L26698
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47382	L26698
58970	L26811

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62311	L26743
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70370	L26594
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72133	L26770

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72146	L26770
72147	L26770
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74230	L26594
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75978	L26737
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76001	L26834
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76499	L26811
76700	L26750

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77373	L26835

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CPT	LCD ID
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CPT	LCD ID
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93971	L26749
93990	L26737
G0130	L26584
G0204	L26764
G0206	L26764

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LCD ID Number: L26500

LCD Title: Automatic Implantable Cardiac Defibrillator (AICD) - 4C-58AB-R1

Contractor's Determination Number: 4C-58

CMS National Coverage Policy:

- *Medicare Benefit Policy Manual* – Pub. 100-02.
- *Medicare National Coverage Determinations Manual* – Pub. 100-03.
- Correct Coding Initiative – *Medicare Contractor Beneficiary and Provider Communications Manual* – Pub. 100-09, Chapter 5.
- Social Security Act (Title XVIII) Standard References, Sections:
    - 1862 (a)(1)(A) Medically Reasonable & Necessary.
    - 1862 (a)(1)(D) Investigational or Experimental.
    - 1833 (e) Incomplete Claim.

Primary Geographic Jurisdiction: Texas

Original Determination Effective Date: 03/01/2008

Revision Effective Date: 02/12/2009

Indications and Limitations of Coverage and/or Medical Necessity:
The following are the **only** covered indications as published in the CMS *National Coverage Determinations (NCD) Manual,* Publication 100-03, Section 20.4 quoted below and as amended by Change Request 3604 for dates of service on or after January 27, 2005). Based on this, these are the **only** circumstances under which providers should submit claims for Medicare payment (even though the ICD-9-CMs used for coverage might otherwise indicate other conditions):

20.4 – Implantable Automatic Defibrillators (Various Effective Dates Below)

A. General

- The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating.

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B. Covered Indications

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 four 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 the past three months.
    d. Had an enzyme-positive MI within the 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.
    f. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one 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 ≤35%.
7. Patients with non-ischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤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.

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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:

c. Patients must be able to give informed consent.
d. Patients must not have:

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

e. Ejection fractions must be measured by angiography, radionuclide scanning or echocardiography.
f. 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 Section 405.201), a trial under the CMS Clinical Trial Policy (NCD, Section 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 reasonableness and necessity 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 Quality Network Exchange (QNet) to the IFMC, which 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:

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- 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.

g. For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.
h. 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 > three months, NYHA Class II or III heart failure and measured LVEF ≤ 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 three 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 one 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 Section 405.201), a trial under the CMS Clinical Trial Policy (NCD, Section 310.1) or a prospective data collection system meeting the following basic criteria:

- Written protocol on file.
- Institutional Review Board review and approval.

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- 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.

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.

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 Section 405.201) and the CMS Routine Clinical Trials Policy (NCD, Section 310.1).

Note: Type of Bill and Revenue Codes DO NOT apply to Part B.

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Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

11	Hospital-inpatient (including Part A)
12	Hospital-inpatient or home health visits (Part B only)
13	Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)
85	Special facility or ASC surgery-rural primary care hospital (eff 10/94)

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0480	Cardiology-general classification

CPT/HCPCS Codes:
Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS) require the use of short CPT descriptors in policies published on the Web.

33240	INSERTION OF SINGLE OR DUAL CHAMBER PACING CARDIOVERTER-DEFIBRILLATOR PULSE GENERATOR
33241	SUBCUTANEOUS REMOVAL OF SINGLE OR DUAL CHAMBER PACING CARDIOVERTER- DEFIBRILLATOR PULSE GENERATOR
33243	REMOVAL OF SINGLE OR DUAL CHAMBER PACING CARDIOVERTER-DEFIBRILLATOR ELECTRODE(S); BY THORACOTOMY
33244	REMOVAL OF SINGLE OR DUAL CHAMBER PACING CARDIOVERTER-DEFIBRILLATOR ELECTRODE(S); BY TRANSVENOUS EXTRACTION
33249	INSERTION OR REPOSITIONING OF ELECTRODE LEAD(S) FOR SINGLE OR DUAL CHAMBER PACING CARDIOVERTER-DEFIBRILLATOR AND INSERTION OF PULSE GENERATOR

ICD-9 Codes that Support Medical Necessity:

The CPT/HCPCS codes included in this LCD will be subjected to “procedure to diagnosis” editing. The following lists include only those diagnoses for which the identified CPT/HCPCS procedures are covered. If a covered diagnosis is not on the

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claim, the edit will automatically deny the service as not medically necessary.Note: Providers should continue to submit ICD-9-CM diagnosis codes without decimals on their claim forms and electronic claims. Medicare is establishing the following limited coverage for CPT/HCPCS codes 33240, 33241, 33243, 33244 and 33249:Covered for:

402.01	Malignant hypertension with congestive heart failure
402.11	Benign hypertension with congestive heart failure
402.91	Unspecified hypertension with congestive heart failure
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease
410.00-410.02	Infarction of anterolateral wall, episode of care unspecified - Infarction of anterolateral wall, subsequent episode of care
410.10-410.12	Infarction of other anterior wall, episode of care unspecified - Infarction of other anterior wall, subsequent episode of care
410.20-410.22	Infarction of inferolateral wall, episode of care unspecified - Infarction of inferolateral wall, subsequent episode of care
410.30-410.32	Infarction of inferoposterior wall, episode of care unspecified - Infarction of inferoposterior wall,subsequent episode of care
410.40-410.42	Infarction of other inferior wall, episode of care unspecified - Infarction of other inferior wall, subsequent episode of care
410.50-410.52	Infarction of other lateral wall, episode of care unspecified - Infarction of other lateral wall, subsequent episode of care
410.60-410.62	True posterior wall infarction, episode of care unspecified - True posterior wall infarction, subsequent episode of care
410.70-410.72	Subendocardial infarction, episode of care unspecified - Subendocardial infarction, subsequent episode of care
410.80-410.82	Infarction of other specified sites, episode of care unspecified - Infarction of other specified sites, subsequent episode of care
410.90-410.92	Infarction, unspecified site, episode of care unspecified - Infarction, unspecified site, subsequent episode of care
412	Old myocardial infarction
414.8	Other specified forms of chronic ischemic heart disease
425.1	Hypertrophic obstructive cardiomyopathy
425.4	Other primary cardiomyopathies
426.82	Long QT syndrome
427.1	Paroxysmal ventricular tachycardia
427.41	Ventricular fibrillation
427.5	Cardiac arrest

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427.89	Other node dysfunction
428.0	Congestive heart failure
428.1	Left heart failure
428.20-428.23	Systolic heart failure, unspecified - Systolic heart failure, acute on chronic
428.30-428.33	Diastolic heart failure, unspecified - Diastolic heart failure, acute on chronic
428.40-428.43	Combined systolic and diastolic heart failure, unspecified - Combined systolic and diastolic heart failure, acute on chronic
428.9	Heart failure, unspecified
746.89	Other heart anomalies
996.72	Other complications due to other cardiac device, implant, and graft

In addition to the limited coverage listed above, Medicare is establishing the following limited coverage for CPT/HCPCS codes 33241, 33243 and 33244:Covered for:

996.04	Mechanical complication of automatic implantable cardiac defibrillator
996.61	Infection and inflammatory reaction due to cardiac device, implant and graft

Diagnoses that DO NOT Support Medical Necessity

All diagnoses not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this LCD.

Documentation Requirements
Documentation supporting medical necessity should be legible, maintained in the patient's medical record and made available to Medicare upon request.

Only one of the diagnoses listed above is required, but the **criteria listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section must be fulfilled** to bill Medicare. The medical record must specify explicitly how the criteria have been fulfilled.

Sources of Information and Basis for Decision
J4 (CO, NM, OK, TX) MAC Integration

TrailBlazer adopted the Noridian Administrative Services, LLC LCD, "Automatic Implantable Cardiac Defibrillator (AICD)," for the Jurisdiction 4 (J4) MAC transition.

Full disclosure of sources of information is found with original contractor LCD.

Other Contractor Local Coverage Determinations

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"Automatic Implantable Cardiac Defibrillator (AICD)," Noridian Administrative Services, LLC LCD, (CO) L18054.

Revision History Explanation
R1
02/12/2009
Added a new limited coverage list in the LCD for codes 33241, 33243 and 33244 to allow coverage for AICD and electrode removal procedures due to AICD infection. Effective date: 01/27/2009.

06/13/2008
LCD effective in TX Part A and Part B and Part A CO and NM 06/13/2008.

03/21/2008
LCD effective in CO Part B 03/21/2008.

03/01/2008
LCD effective in NM Part B and OK Part A and Part B 03/01/2008
12/20/2007 Consolidated LCD posted for notice effective: 12/20/2007.

Last Reviewed On Date: 04/14/2009

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