

Policy: MP140

Section: Medical Benefit Policy

Subject: Automatic Implantable Cardioverter-Defibrillator

I. Policy: Automatic Implantable Cardioverter-Defibrillator

II. Purpose/Objective:

To provide a policy of coverage regarding Automatic Implantable Cardioverter-Defibrillator

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:

The automatic implantable cardioverter-defibrillator is an electronic device designed to reduce the risk of sudden cardiac death by monitoring a member's heart rate, recognizing life-threatening arrhythmias such as ventricular fibrillation and ventricular tachycardia, and by automatically delivering an electrical shock to terminate the arrhythmia. Automatic implantable cardioverter-defibrillator (AICD) devices have also been incorporated with cardiac resynchronization therapy, allowing simultaneous treatment of congestive heart failure with ventricular conduction dysfunction and sudden cardiac death caused by ventricular arrhythmias.

INDICATIONS:

1. Automatic Implantable Cardioverter-Defibrillator

Members must be under the care of, and the device must be recommended by a cardiologist sub-specializing in electrophysiology.

Automatic implantable cardioverter-defibrillator implantation is considered medically necessary when **any** of the following conditions are present and are not due to a transient or reversible cause:

- Documented cardiac arrest secondary to ventricular fibrillation; **or**
- Documented sustained ventricular tachyarrhythmia, spontaneous or induced during an electrophysiology (EP) study, not associated with a myocardial infarction; **or**
- Coronary artery disease, with a left ventricular ejection fraction (LVEF) \leq 35% after a previous myocardial infarction (MI), and an inducible sustained ventricular tachyarrhythmia documented by an EP study; (the EP study must be performed at least 4 weeks after the qualifying MI); **or**
- Medical record documentation of inherited or familial conditions with a high risk of ventricular tachyarrhythmia (e.g., long QT syndrome or hypertrophic cardiomyopathy); **or**
- Prior MI, with a LVEF of \leq 30% and a QRS duration \geq 120 ms.; **or**
- Ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction, New York Heart Association (NYHA) Class II and III heart failure and measured left ventricular ejection fraction (LVEF) less than or equal to 35%; **or**
- Members who meet all current CMS coverage requirements for a cardiac resynchronization therapy device and have NYHA Class IV heart failure; **or**
- Non Ischemic dilated cardiomyopathy (NIDCM) greater than 3 months, NYHA Class II or III heart failure, and a measured LVEF less than or equal to 35%

2. Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Biventricular pacing/CRT is considered medically necessary for members who meet **all** of the following criteria:

- Moderate to severe congestive heart failure (New York Heart Assn. Functional Class III or IV)*
- Member remains symptomatic in spite of optimized pharmacotherapy
- Left ventricular ejection fraction of 35% or less
- QRS duration of 120 ms or greater

3. Automatic Implantable Cardioverter-Defibrillator/ Cardiac Resynchronization Therapy Defibrillator (AICD/CRT)

For members who are at high risk of sudden cardiac death secondary to ventricular arrhythmias, the combined AICD/CRT device is considered medically necessary when, in addition to either 1 or 2 above and any of the following criteria are also met:

- A documented cardiac arrest due to ventricular arrhythmia; **or**
- Documented, sustained ventricular tachyarrhythmia (spontaneous or induced during an electrophysiology study), not associated with an acute myocardial infarction; **or**
- Documented familial or inherited conditions that carry a high risk of life threatening ventricular tachyarrhythmia (e.g. long QT syndrome, Brugada syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia, or hypertrophic cardiomyopathy); **or**
- Coronary artery disease with a documented myocardial infarction, a left ventricular ejection fraction of 35% or less, and inducible, sustained ventricular tachyarrhythmia or ventricular fibrillation during an electrophysiology study; **or**
- Documented prior myocardial infarction, and a left ventricular ejection fraction 30% or less, but the member does not have:
 1. NYHA classification IV; or
 2. cardiogenic shock or symptomatic hypotension while in stable baseline rhythm; or
 3. a coronary artery bypass graft or percutaneous transluminal coronary angioplasty within the past 3 months; or

- 4. an enzyme positive MI within the past 40 days; or
- 5. clinical symptoms that would make them a candidate for coronary revascularization; or
- 6. any disease other than cardiac disease associated with a likelihood of survival less than 1 year
- Ischemic dilated cardiomyopathy (ICDM), documented prior MI, NYHA class II or III heart failure and LVEF of 35% or less; **or**
- Member meets all current CMS coverage requirements for a cardiac resynchronization therapy device and have NYHA class IV heart failure; **or**
- Non-ischemic dilated cardiomyopathy for greater than 3 months, NYHA class II or III heart failure and LVEF of 35% or less

4. **Subcutaneous Implantable Cardioverter-Defibrillator**

Subcutaneous cardioverter-defibrillator (S-ICD) devices are considered medically necessary for the following at-risk individuals when the medically necessary criteria for implantable cardioverter-defibrillator therapy have been met and at least one of the following conditions are present:

- lack of venous access, or the need to preserve existing vascular access due to chronic dialysis; or
- removal of a transvenous ICD due to a complication, with ongoing need for ICD therapy
- Individuals with endocarditis; prosthetic valves; or immunocompromised and at significant risk of infection
- Pediatric members with anticipated long-term need for ICD therapy

Note: The FDA defines pediatrics as birth through the 21st year of life.

LIMITATIONS:

The device must be FDA approved. **Note:** Those individuals enrolled in the Medicare Business Segment may be eligible for non-FDA approved devices if the device is part of an approved Category B Investigative Device Exemption clinical trial.

EXCLUSIONS:

Subcutaneous cardioverter-defibrillators are considered experimental, investigational, or unproven for all indications when the above criteria are not met.

Automatic implantable cardioverter-defibrillator implantation is not considered medically necessary when the member has any of the following situations:

- New York Heart Association Classification IV congestive heart failure
- Clinical symptoms that would make the member a candidate for coronary revascularization
- A coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty within the past 3 months
- Cardiogenic shock or symptomatic hypotension during stable baseline rhythm
- When other disease processes are present that are clearly associated with a likelihood of survival less than 1 year.

NYHA Classification System for Heart Failure

Class I: No limitation of physical activity. No shortness of breath, fatigue, or heart palpitations with ordinary physical activity.
Class II. Slight limitation of physical activity. Shortness of breath, fatigue, or heart palpitations with ordinary physical activity, but patients are comfortable at rest.
Class III. Marked limitation of activity. Shortness of breath, fatigue, or heart palpitations with <i>less than</i> ordinary physical activity, but patients are comfortable at rest.
Class IV. Severe to complete limitation of activity. Shortness of breath, fatigue, or heart palpitations with <i>any</i> physical exertion and symptoms appear even at rest.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 00534 Anesthesia for transvenous insertion or replacement of pacing cardioverter-defibrillator
- 33202 Insertion of epicardial electrode(s); open incision (eg, thoracotomy, median sternotomy, subxiphoid approach) [when specified as ICD]
- 33203 Insertion of epicardial electrode(s); endoscopic approach (eg, thoracoscopy, pericardioscopy) [when specified as ICD]
- 33216 Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator [when specified as ICD]
- 33217 Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator [when specified as ICD]
- 33220 Repair of 2 transvenous electrodes for permanent pacemaker or pacing cardioverter-defibrillator
- 33223 Revision of skin pocket for cardioverter-defibrillator
- 33240 Insertion of implantable defibrillator pulse generator only; with existing single lead
- 33230 Insertion of implantable defibrillator pulse generator only; with existing dual leads
- 33231 Insertion of implantable defibrillator pulse generator only; with existing multiple leads
- 33249 Insertion or replacement of permanent implantable defibrillator system with transvenous lead(s), single or dual chamber
- 33270 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
- 33271 Insertion of subcutaneous implantable defibrillator electrode
- 33272 Removal of subcutaneous implantable defibrillator electrode
- 33273 Repositioning of previously implanted subcutaneous implantable defibrillator electrode
- 93640 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;
- 93641 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
- 93644 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)

- C1721 Cardioverter-defibrillator, dual chamber (implantable)
- C1722 Cardioverter-defibrillator, single chamber (implantable)
- C1777 Lead, cardioverter-defibrillator, endocardial single coil (implantable)
- C1882 Cardioverter-defibrillator, other than single or dual chamber (implantable)
- C1895 Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
- C1896 Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
- G0448 Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

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LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/04

Revised: 7/05 (coding, expanded CMS indication); 5/06 (addition of CRT-D, remove prior auth); 5/07, 6/14 (added exclusion); 5/16 (add S-ICD criteria); 5/19 (revise ICD/CRT criteria)

Reviewed: 5/08, 5/09, 6/10, 6/11, 6/12, 6/13, 6/14; 5/15, 5/17, 5/18