**Policy:** Surgically implanted Cardioverter defibrillators (ICD) are a class of medical devices designed to monitor a patient’s heart rate and rhythm, recognize a life-threatening ventricular arrhythmia such as ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias. ICDs may be used for primary prevention in patients who are determined to be at high risk for sudden cardiac death, even though they may not yet have demonstrated an episode of VT or VF; or secondary prevention, in patients who have experienced at least one documented episode of VT or VF. Certain conditions may also exist that require atrial pacing to support an AV node dysfunction. When the device is inserted along with a cardiac pacemaker, the particular type of pacemaker chosen must meet generally accepted InterQual criteria for the type of pacemaker requested as defined in this policy.

**Procedure:** All requests for ICDs or pacemaker with ICD will be treated as single chamber device requests unless specifically requested otherwise. This generally elective procedure must be prior-authorized by Meridian Health Plan (MHP) unless to do so would compromise the patients’ health. Emergent cases will be subject to post service appeal review by MHP with the possibility of retrospective denial if criteria is not met that supports use of the device.

1. InterQual criteria will be used for Single Chamber Implantable Cardioverter Defibrillator Device, noting the additional Medicare conditions listed under the special instructions section of this policy. Also note that in applying InterQual Criteria, ejection fractions must be measured by angiography, radionuclide scanning or echocardiography and 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. There are circumstances when a dual chamber implantable Cardioverter Defibrillator device may be indicated but noting that without a pacing indication, dual-chamber ICDs do not clearly have a clinical advantage to justify the significantly greater complication risk associated with the dual chamber devices. Because of this concern, Dual-Chamber Implantable Cardioverter Defibrillator Devices must meet the general requirements for an ICD device, as well as meeting the additional criteria below:

i. ACC/AHA/HRS Class I indication where any of the following apply and indication clearly documented in the record (examples of conditions appropriate for this include sick sinus syndrome, high grade AV block, history of or planned AV nodal ablation)
   a. Atrioventricular (AV) synchrony during pacing is needed
   b. There is a suspected abnormality of AV conduction or increased risk for future AV block
   c. Atrial pacing would be needed or there is a need for availability of rate response

ii. If used for atrial fibrillation, there must be documentation that prior treatment was either ineffective or not tolerated.

When applying the criteria that involves Myocardial Infarction (MI), 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).

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.

Rationale: Automatic implantable cardiac defibrillators were first used in survivors of near sudden cardiac death. More recently, there has developed a broader application, that of using AICDs as primary preventive therapy in patients who demonstrate a risk for sudden cardiac death, even though they may not have actually experienced a serious ventricular arrhythmia. The medical policy is based primarily on the Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities in the Journal of American College of Cardiology. Also, the results of the two MADIT (Multicenter Automatic Defibrillator Implantation) studies, which compared the use of an AICD with conventional therapy in patients with coronary artery disease and a history of myocardial infarction (MI), and who have a reduced ventricular ejection fraction. Studies have shown conclusively that patient outcomes are improved by the use of AICD versus conventional treatment in patients who are at risk for sudden death from ventricular arrhythmia. Although not all patients with a history of MI are at risk, diagnostic studies such as T-wave alternans measurement and electrophysiologic studies may be used to identify potential candidates for AICD implantation. There is insufficient evidence that AICD implantation improves outcomes in patients with very recent acute MI, those with advanced congestive heart failure, or those whose coronary artery disease can be treated with coronary revascularization, or those who have had a recent revascularization.
Special Instructions:

Medicare additional conditions for ICDs

For the following conditions only the general criteria of the policy must be met:

1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause.

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.

3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy.

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

For all other conditions (primary prevention of sudden cardiac death) the following conditions must also be 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. 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.

d. 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.
CPT/HCPCS Codes:
33208, 33202, 33203, 33206, 33207, 33213, 33214, 33215, 33216, 33218, 33220, 33221, 33222, 33223, 33224, 33225, 33226, 33227, 33228, 33229, 33231, 33234, 33235, 33236, 33237, 33238, 33240, 33241, 33249, 33250, 33263, 33264, 33282

Approved by: ____________________________          Date: 10/20/2015
Corporate Chief Operating Officer

Reviewed and approved by Medical Policy and Procedures Committee: Date: 08/20/2015
Reviewed and approved by Medical Policy Operations Committee: Date: 08/28/2015
Reviewed and approved by Physician Advisory Committee: Date: 09/25/2015
Reviewed and approved by Corporate Compliance Committee: Date: 10/20/2015

References: