BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	**MANUAL:** MEDICAL POLICY
	REFERENCE NO.: MPO-490-0169
EFFECTIVE DATE August 1, 2014	**SUBJECT:** Cardiac Rhythm Devices

Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice. Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure. In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

I. DESCRIPTION:

The automatic implantable cardioverter defibrillator (ICD) is a device consisting of a pulse generator and electrodes for sensing and defibrillating. It is 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.

The wearable cardioverter-defibrillator (WCD) is an external device that is intended to perform the same tasks as an ICD, without requiring invasive procedures. It consists of an electrode vest and a connected monitor/alarm which interprets the cardiac rhythm and determines when a counter shock is necessary.

The biventricular pacemaker, used for the treatment of congestive heart failure, consists of a pulse generator and three wires (leads) that deliver electrical impulses to the heart. This device differs from a standard pacemaker in that it has three leads instead of one or two leads in order to stimulate both the right and left ventricles

II. BENEFIT POLICY STATEMENT:

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

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Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

III. MEDICAL POLICY STATEMENT:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

A. BCNEPA will provide coverage for biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) when medically necessary.

1. Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) may be considered medically necessary as a treatment of heart failure in patients who meet all of the following criteria:

<u>New York Heart Association class III or IV</u>

a) Left ventricular ejection fraction ≤35%

b) Sinus rhythm

c) QRS duration of ≥120–130* msec; and

d) Patients treated with a stable pharmacological medical regimen prior to implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and/or diuretics.

<u>New York Heart Association class II</u>

a) Left ventricular ejection fraction <u>≤</u>30%

b) Sinus rhythm

c) QRS duration of ≥120–130* msec, and

d) Patients treated with a stable pharmacological medical regimen prior to implant, such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker (or angiotensin receptor blocker), digoxin, and/or diuretics.

***** The FDA-labeled indications for QRS duration vary by device. For some devices, FDA approval is based on QRS duration of ≥130 (e.g., InSync® device) while for others it is based on QRS duration ≥120msec (e.g., CONTAK CD® CRT-D System). These differences in QRS duration arise from differences in the eligibility criteria in the trials on which the FDA approval is based.

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2. Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) as a treatment of heart failure in patients who do not meet the criteria above are considered not medically necessary.

3. Biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD) are considered investigational as a treatment for patients with NYHA class I heart failure.

4. Biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator (i.e., a combined biventricular pacemaker/ICD), are considered investigational as a treatment for heart failure in patients with atrial fibrillation.

B. BCNEPA will not provide coverage for an intrathoracic fluid monitoring sensor as a component of a biventricular pacemaker as this is considered investigational.

C. BCNEPA will not provide coverage for triple-site (triventricular) CRT, using an additional pacing lead, as this is considered investigational.

Implantable Cardioverter Defibrillator (ICD)

D. BCNEPA will provide coverage for an automatic implantable cardioverter-defibrillator in adults when medically necessary.

1. The use of the automatic implantable cardioverter-defibrillator (ICD) may be considered medically necessary for primary prevention in patients who meet the following criteria:

a) Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class II or class III symptoms, a history of myocardial infarction at least 40 days before ICD treatment and left ventricular ejection fraction of 35% or less; or

b) Ischemic cardiomyopathy with NYHA functional class I symptoms, a history of myocardial infarction at least 40 days before ICD treatment, and left ventricular ejection fraction of 30% or less; or

c) Nonischemic dilated cardiomyopathy and left ventricular ejection fraction of 35% or less, after reversible causes have been excluded, and the response to optimal medical therapy has been adequately determined; or

d) Hypertrophic cardiomyopathy (HCM) with 1 or more major risk factors for sudden cardiac death (history of premature HCM-related sudden death in 1 or more first-degree relatives younger than 50 years; left ventricular hypertrophy greater than 30 mm; 1 or more runs of nonsustained ventricular tachycardia at heart rates of 120 beats per minute or greater on 24-hour Holter monitoring; prior unexplained syncope inconsistent with neurocardiogenic origin) and judged to be at high risk for sudden cardiac death by a physician experienced in the care of patients with HCM.

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2. The use of the automatic implantable cardioverter-defibrillator (ICD) may be considered medically necessary for secondary prevention in patients who meet the following criteria:

   a) Patients with a history of a life-threatening clinical event associated with ventricular arrhythmic events such as sustained ventricular tachyarrhythmia, after reversible causes (e.g., acute ischemia) have been excluded.

3. The use of the automatic implantable cardioverter-defibrillator (ICD) in patients not meeting criteria above is considered not medically necessary.

4. The use of the ICD is considered investigational in primary prevention patients who:

   a) Have had an acute myocardial infarction (i.e., less than 40 days before ICD treatment);

   b) Have NYHA Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device);

   c) Have had cardiac revascularization procedure in past 3 months (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]) or are candidates for a cardiac revascularization procedure; or

   d) Have noncardiac disease that would be associated with life expectancy less than 1 year.

E. BCNEPA will provide coverage for an automatic implantable cardioverter-defibrillator in pediatric patients when medically necessary.

1. The use of the ICD may be considered medically necessary in children who meet any of the following criteria:

   a) Survivors of cardiac arrest, after reversible causes have been excluded;

   b) Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; or

   c) Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.

2. The use of the ICD is considered investigational for all other indications in pediatric patients.

F. The use of a subcutaneous ICD is considered investigational for all indications in adult and pediatric patients.

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Wearable Cardioverter-Defibrillators

G. BCNEPA will provide coverage for a wearable cardioverter-defibrillator when medically necessary.

1. Use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death is considered medically necessary as interim treatment for those who:

a) Meet the criteria for an implantable cardioverter-defibrillator (see above); and

b) Have a temporary contraindication to receiving an ICD, such as a systemic infection, at the current time; and

c) Have been scheduled for an ICD placement or who had an ICD removed and have been rescheduled for placement of another ICD once the contraindication is treated.

H. BCNEPA will not provide coverage for the use of wearable cardioverter-defibrillators for the prevention of sudden cardiac death for the following indications as they are considered investigational and, therefore, not covered because the safety and effectiveness of these services cannot be established by review of the available published peer-reviewed literature:

1. Patients in the immediate (i.e., less than 40 days) period following an acute myocardial infarction.

2. Patients post-CABG [coronary artery bypass graft] surgery.

3. Patients with newly diagnosed non-ischemic cardiomyopathy.

4. Women with peripartum cardiomyopathy.

5. High-risk patients awaiting heart transplant

6. All other indications not identified above as medically necessary.

IV. DEFINITIONS:

N/A

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CODING:

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- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

PROCEDURE CODES

0319T	0324T	93292	C1882	K0609
0320T	0325T	93745	E0617	
0321T	0326T	C1721	K0606	
0322T	0327T	C1722	K0607	
0323T	0328T	C1777	K0608	

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