CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 5/15/2011
Next Review Date 5/15/2012
Coverage Policy Number 0058

Subject **External Counterpulsation**

Table of Contents

Hyperlink to Related Coverage Policies

Heart Transplantation
Spinal Cord Stimulation
Transmyocardial Revascularization (TMR) and Percutaneous Myocardial Revascularization (PMR)
Ventricular Assist Devices (VADs)

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.*

Coverage Policy

CIGNA covers a single course of up to 35 sessions of external counterpulsation (ECP) as medically necessary for the treatment of chronic stable angina pectoris as defined by the New York Heart Association [NYHA] Functional Classification III or IV or equivalent when BOTH of the following criteria are met:

- there is failure, contraindication or intolerance to pharmacological management
- the individual is not a candidate for angioplasty or revascularization **OR** has undergone angioplasty or revascularization and continues to be symptomatic

CIGNA does not cover external counterpulsation for ANY other indication including but not limited to the following because it is considered experimental, investigational or unproven (this list may not be all-inclusive):

- arrhythmia
- aortic insufficiency
- congestive heart failure
- erectile dysfunction
- fatigue/malaise
- hepatorenal syndrome
- peripheral vascular disease or phlebitis
- restless leg syndrome

- retinal artery occlusion
- severe hypertension (>180/100 mm Hg)
- stroke
- sudden deafness and tinnitus
- unstable angina
- vertebrobasilar insufficiency

General Background

External counterpulsation (ECP) has been proposed as a noninvasive procedure that seeks to improve cardiovascular functioning in patients with chronic stable angina pectoris whom are refractory to medical and/or surgical management. ECP involves the sequential inflation of three sets of lower-extremity cuffs during diastole, leading to increased venous return and cardiac output, systolic unloading, and augmentation of the coronary artery perfusion pressure. The precise mechanisms accounting for the clinical benefits of ECP are not completely understood but include improved endothelial function, reduced aortic impedance, enhanced coronary artery collateral blood flow, and improved hemodynamics. The immediate hemodynamic effects of ECP are similar to intra-aortic balloon pump counterpulsation (Campbell, et al., 2008; Michaels, et al., 2006; Arora, et al., 1999).

A full course of ECP typically involves five hours of treatment per week, delivered in one- to two-hour sessions for seven weeks, for a total of 35 hours of treatment (Brosche, et al., 2004; Arora, et al., 1999). Michaels et al. (2005) assessed the frequency, efficacy, predictors, and long-term success of repeat ECP therapy in relieving angina in a large cohort of patients who had chronic angina and had undergone a full course of ECP. Patients who underwent repeat ECP did benefit from the two courses of therapy, but they did not sustain the symptomatic improvement. Of the patients who had repeat ECP, 59% also had class 0 to II angina compared with 82% of those who did not undergo repeat ECP ($p<0.001$). Nitroglycerin use was more common in patients who underwent repeat ECP (63%) than in those who did not (45%; $p<0.0001$).

The reported adverse events or side effects that have been related to ECP therapy include leg or waist pain, skin abrasion or ecchymoses, bruises in patients using Coumadin when INR dosage is not adjusted, paresthesias, worsening of congestive heart failure (CHF) in patients with severe arrhythmia, myocardial infarction (MI), angina, chest pain, arrhythmia, and pulmonary edema (Manchanda, et al., 2007; ECR, 2000).

ECP is generally considered safe in patients without specific contraindications. According to the manufacturer's technical and professional guides for ECP therapy, the following conditions are considered precautions or contraindications to ECP therapy (Vasomedical, 2009; Cardiomedics, 2005):

- abdominal aortic aneurysm > 3.0 cm
- severe aortic regurgitation/severe aortic valve disorder
- phlebitis
- deep vein thrombosis
- coronary artery bypass after three months acceptable, preferable six months
- angiogram/interventions after two weeks
- hypertension > 180/110 mm Hg, hypotension < 80/50 mm Hg
- uncontrolled atrial fibrillation (heart rate 50–90 beats per minute)
- peripheral vascular disease
- left ventricular hypertrophy
- severe pulmonary disease
- bleeding diathesis (coumadin therapy with PT/INR > 3.0)
- sustained arrhythmias
- pregnancy

Much of the published literature has evaluated ECP for cardiac-related conditions such as angina pectoris and CHF. ECP has also been proposed as treatment for several other conditions (e.g., restless leg syndrome,

sudden deafness, stroke, erectile dysfunction, hepatorenal syndrome, retinal artery occlusion) (Manchanda, et al., 2007).

U.S. Food and Drug Administration (FDA)
The FDA granted 510(k) approval for the CardiAssist™ ECP System in 1980. Since then, additional ECP devices have received 510(k) approval for use in treating stable and unstable angina pectoris, acute MI, cardiogenic shock, and CHF (FDA, 2008).

Chronic Stable Angina Pectoris
Chronic, intractable or refractory, stable angina pectoris, also known as end-stage coronary artery disease (CAD), is defined as "a chronic condition characterized by the presence of angina caused by coronary insufficiency in the presence of CAD which cannot be controlled by a combination of medical therapy, angioplasty and coronary bypass surgery. The presence of reversible myocardial ischemia should be clinically established to be the cause of the symptoms. Chronic is defined as a duration of more than three months" (Mannheimer, et al., 2002). Myocardial ischemia relates to the insufficient supply of oxygenated blood to the myocardium due to atherosclerosis, coronary artery spasm, thrombosis, and a variety of other medical conditions. Of the symptoms related to poor circulation of blood (e.g., dizziness and shortness of breath) the cardinal symptom is angina. Angina is characterized by severe chest pain with radiation of pain to the jaw or left arm (Deer and Raso, 2006; Mannheimer, et al., 2002; Eliasson, et al., 1996).

Anginal pain is most often treated with medication (e.g., calcium-channel blockers, nitrates, and Beta (ß)-blocking agents), revascularization surgery (i.e., coronary artery bypass grafting [CABG] and percutaneous transluminal coronary angioplasty [PTCA]) or non-surgical revascularization (e.g., balloon angioplasty, intracoronary stenting, rotational atherectomy). Despite medical and surgical treatment, there is a subset of patients with CAD who do not respond to conventional medical therapy, are not candidates for revascularization procedures, or who have had previous revascularization surgery and in whom anginal pain persists (DeJongste, 2000). Few options exist for patients with chronic stable anginal pain resistant to conventional treatment. Therapies aimed at those patients with chronic stable angina pectoris refractory to conventional treatment include: transmyocardial laser revascularization (TMR), thoracic epidural anesthesia, ECP, transcutaneous electrical nerve stimulation (TENS), and spinal cord stimulation (SCS). There is limited evidence directly comparing these multiple therapeutic methods in the peer-reviewed medical literature (Bondesson, et al., 2008; Eliasson, et al., 1996).

To assist physicians in grading the severity of angina pectoris, the New York Heart Association (NYHA) and the Canadian Cardiovascular Society (CCS) published functional classifications based upon clinical severity and prognosis for patients with cardiac disease. The classifications relate symptoms to everyday activities and quality of life (QOL). The scientific studies for ECP have typically included those patients who are categorized as CCS class III or class IV. CCS is a modification of the NYHA functional classification that allows patients to be categorized in more specific terms (Appendix A) (Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; CCS, 1976).

ECP has been clinically studied since the 1960's. The earliest studies were done in the areas of cardiogenic shock and acute MI. Recent studies have focused primarily on angina and heart failure.

Literature Review: Although the evidence supporting the use of ECP comes from a number of uncontrolled studies and case series reports, analyses of patient registry data and limited controlled studies, a single course of ECP has become the standard of care for a subset of individuals with chronic stable angina as defined by the New York Heart Association [NYHA] Functional Classification III or IV or equivalent in patients who have failure, contraindication or intolerance to pharmacological management and are not considered candidates for angioplasty or revascularization or in patients with severe chronic stable angina who have undergone angioplasty or revascularization and continue to be symptomatic (Shah, et al., 2010; Braith, et al., 2010; Bondesson, et al., 2008; Campbell, et al., 2008; Erdling, et al., 2008; Loh, et al., 2008; Lawson, et al., 2006; Loh, et al., 2006; Pettersson, et al., 2006; Ochao, et al., 2006; Nichols, et al., 2006; Michaels, et al., 2004; Holubkov, et al., 2002; Michaels, et al., 2002; Barsness, et al., 2001; Lawson, et al., 2000a; Arora, et al., 1999; Lawson, et al., 2000a, 1998, 1996a, 1996b, 1995).

Professional Societies/Organizations: The ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) 2005 practice guideline for percutaneous coronary intervention states that ECP appears to

decrease symptoms in patients with refractory angina who have no vessels suited for revascularization (Smith, et al., 2006).

The American College of Physicians clinical practice guideline for the primary care management of chronic stable angina and asymptomatic suspected or known CAD states under the category of alternative therapies for patient with refractory angina that evidence is lacking for the use of ECP. ECP should be used only in patients who cannot be managed adequately by medical therapy and who are not candidates for interventional or surgical revascularization (Snow, et al., 2004).

The ACC/AHA 2002 guideline update for the management of patients with chronic stable angina assigns a level of evidence of Class IIb (the usefulness/efficacy is less well established by evidence/opinion). This suggests there may be some benefit, but additional clinical trial data is needed before ECP can be recommended definitively (Gibbons, et al., 2003). ECP was not mentioned in the 2007 Chronic Angina Focused Update of the ACC/AHA 2002 Guidelines for the Management of Patients With Chronic Stable Angina (Fraker, et al., 2007).

ECP for Other Indications
The safety, effectiveness and long-term outcomes of ECP for conditions other than chronic stable angina pectoris has not been established in the peer-reviewed medical literature (this list may not be all inclusive) (Xin, et al., 2010; Thakkur, et al., 2010; Alexandrov, et al., 2008; Manchanda, et al., 2007; Lawson, et al., 2007; Soran, et al., 2006; Lawson, et al,. 2005; Werner, et al., 2005; Werner, et al., 2004; Lawson, et al., 2001; Taguschi, et al., 2000):

- arrhythmia
- aortic insufficiency
- congestive heart failure
- erectile dysfunction
- fatigue/malaise
- hepatorenal syndrome
- peripheral vascular disease or phlebitis
- restless leg syndrome
- retinal artery occlusion
- severe hypertension (>180/100 mm Hg)
- stroke
- sudden deafness and tinnitus
- unstable angina
- vertebrobasilar insufficiency

Literature Review
Heart Failure: In a randomized controlled trial, Feldman et al. (2005, 2006) examined the effects of ECP in the treatment of CHF. The Prospective Evaluation of Enhanced External Counterpulsation in Congestive Heart Failure (PEECH) study randomized 187 patients with mild or moderate heart failure to receive either 35 one hour sessions of ECP treatment in addition to optimal pharmacotherapy, or pharmacotherapy alone. Prior to randomization, medical therapy was optimized for all individuals. Only individuals with stable heart failure (secondary to ischemic heart disease or idiopathic-dilated cardiomyopathy), with LVEF < 35 and NYHA class I or II were eligible for inclusion. The study evaluated changes in: exercise duration (percentage of individuals with increase ≥60 seconds on treadmill, absolute change [seconds]); peak volume of oxygen uptake (Vo2) (percentage of individuals with increase ≥1.25 ml/min/kg); quality of life measures (SF-36 and Minnesota Living with Heart Failure Questionnaire) and New York Heart Association (NYHA) functional classification status. Although the study reports improved exercise tolerance and NYHA functional classification in ECP-treated individuals, several study design flaws undermine the reliability of the study findings. The patients undergoing ECP could not be blinded, increasing likelihood of the placebo effect. Fewer patients completed the study in the active treatment group (76%) than in the control group (86%), largely due to more patients in the ECP group discontinuing due to an adverse experience (11.8% ECP versus 3.2% control), suggesting that there may be a difference that affects the outcome). Adverse events that occurred in relation to the application of ECP therapy resulting in discontinuation included sciatica (one patient), leg pain (one patient), and arrhythmia, which interfered with application of the therapy (two patients). One other ECP subject suffered a non–Q-wave myocardial infarction during the treatment period not attributable to the therapy. During the follow-up period, six

additional subjects from the ECP group discontinued due to worsening heart failure. Adverse events in the control group leading to discontinuance included two deaths during the treatment period and one instance of atrioventricular block during the follow-up period. The short follow-up period (six months) limits conclusions regarding the durability of treatment effects. Exclusion of NYHA functional class III and IV, limit the ability to apply the study findings to the general population of patients with heart failure who are seen in clinical practice. Methodological flaws associated with this study precludes the ability to generalize findings and draw strong conclusions regarding the impact on health outcomes.

Soran et al. (2006) used IEPR data to evaluate the two-year outcomes of patients (n=363) who had severe LV dysfunction treated with ECP for angina pectoris. Immediately post-ECP therapy, 77% of the patients improved more than one angina class, and 18% had no angina. At two years, 73% (n=265) of the patients completed follow-up, and 55% had sustained improvement in angina class. At baseline, 58% improved quality of life compared to 63% at two-year follow-up. This study had no control group to assess outcomes

In a prospective cohort study, Lawson et al. (2005) studied the immediate and one-year benefit from ECP in angina patients with diastolic versus systolic heart failure (n=746). Regardless of the degree of left ventricular dysfunction, ECP benefited anginal symptoms in heart failure patients. However, more rigorous evaluation of the impact of ECP on clinical outcomes will require a randomized trial. Lawson et al. (2001) analyzed ECP results of 1957 patients, 548 (28%) of whom had histories of CHF at baseline; all 1957 patients were reassessed at six months. Immediately after ECP, 68% of the CHF cohort demonstrated a CCS class improvement of one or more levels, and 0.9% demonstrated a worsening in functional class. The improvement was maintained over the six-month period. In addition, 58% felt their overall health had improved, and 55% felt their quality of life had improved. The mean improvement in CCS functional angina class was less in the CHF cohort than in the non-CHF cohort, and the CHF cohort was significantly more likely to discontinue treatment, generally due to exacerbation of CHF symptoms.

Professional Societies/Organizations: The 2005 ACC guidelines for the evaluation and management of chronic heart failure in the adult state that early trials of ECP therapy in patients with heart failure and low EF have been encouraging, but until more data is available, routine ECP use for the management of patients with symptomatic reduced LVEF is not recommended (Hunt, 2005). The ACC commented to the Center for Medicare & Medicaid Services (CMS) that they agree with their March 2006 coverage decision to not cover ECP therapy for heart failure (CMS, 2006). This information was not updated in the 2009 focused update.

In 2007, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines (Writing Committee to revise the 2002 Guidelines for the Management of Patients with Unstable Angina/Non–ST-Elevation Myocardial Infarction [UA/NSTEMI]) updated the UA/NSTEMI guideline. Other anti-ischemic therapies are discussed in the guideline under the use of anti-ischemic therapies stating, “Other less extensively studied therapies for the relief of ischemia, such as spinal cord stimulation and prolonged external counterpulsation are under evaluation. Most experience has been gathered with spinal cord stimulation in “intractable angina”, in which anginal relief has been described. They have not been applied in the acute setting for UA/NSTEMI” (Anderson, et al., 2007). There has been no update to this guideline since 2007.

Summary
Although external counterpulsation (ECP) has been cleared by the U.S. Food and Drug Administration (FDA) to treat stable or unstable angina pectoris, acute myocardial infarction (MI), cardiogenic shock and heart failure, there is currently insufficient evidence to support the use of a single course of ECP treatment for conditions other than chronic stable angina pectoris as defined by the New York Heart Association [NYHA] Functional Classification III or IV or equivalent in patients who have failure, contraindication or intolerance to pharmacological management and are not considered candidates for angioplasty or revascularization or in patients with severe chronic stable angina pectoris who have undergone angioplasty or revascularization and continue to be symptomatic.

There is insufficient evidence in the peer-reviewed, published scientific literature to support the clinical utility of ECP for the treatment of any of the following conditions (this list may not be all-inclusive):

- arrhythmia
- aortic insufficiency
- congestive heart failure

- erectile dysfunction
- fatigue/malaise
- hepatorenal syndrome
- peripheral vascular disease or phlebitis
- restless leg syndrome
- retinal artery occlusion
- severe hypertension (>180/100 mm Hg)
- stroke
- sudden deafness and tinnitus
- unstable angina
- vertebrobasilar insufficiency

Appendix A

New York Heart Association and Canadian Cardiovascular Society Functional Classifications Class	New York Heart Association Functional Classification	Canadian Cardiovascular Society Functional Classification
I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous or rapid or prolonged exertion at work or recreation.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.

IV	Patient with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.
(Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).		

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	**Description**
92971	Cardioassist-method of circulatory assist; external
93799†	Unlisted cardiovascular service or procedure

†**Note: Covered up to a single course of 35 visits when used to report external counterpulsation for medically necessary conditions outlined in coverage position.**

HCPCS Codes	**Description**
G0166	External counterpulsation, per treatment session

ICD-9-CM Diagnosis Codes	**Description**
413.9	Other and unspecified sagina pectoris
414.00-414.07	Coronary artherosclerois
V15.1	Personal history of surgery to heart and great vessels, presenting hazards to health

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	**Description**
333.94	Restless legs syndrome [RLS]
362.30	Unspecified retinal vascular occlusion
388.30 – 388.32	Tinnitus
401.0	Essential hypertension, malignant
401.9	Hypertension
411.1	Intermediate coronary syndrome
413.0	Angina decubitus
413.1	Prinzmetal angina
424.1	Aortic valve disorders
427.9	Unspecified cardiac dysrhythmia
428.0	Congestive heart failure, unspecified
433.00-433.01	Occlusion and stenosis of basilar artery

434.91	Unspecified cerebral artery occlusion with cerebral infarction
435.3	Vertebrobasilar artery syndrome
443.0-443.9	Other peripheral vascular disease
451.0-451.9	Phlebitis and thrombophlebitis
572.4	Hepatorenal syndrome
607.84	Impotence of organic origin
786.05	Shortness of breath
786.09	Other dyspnea and respiratory abnormalities
786.50	Chest pain
780.79	Malaise and fatigue
V57.9	Unspecified rehabilitation procedure
	All other codes

References

1. Alexandrov AW, Ribo M, Wong KS, Sugg RM, Garami Z, Jesurum JT, et al. Perfusion augmentation in acute stroke using mechanical counter-pulsation-phase IIa: effect of external counterpulsation on middle cerebral artery mean flow velocity in five healthy subjects. Stroke. 2008 Oct;39(10):2760-4. Epub 2008 Jul 24.

2. American Heart Association (AHA). External Counterpulsation. Accessed March 23, 2011. Available at URL address: http://www.americanheart.org/presenter.jhtml?identifier=4577

3. American Heart Association (AHA). 1994 Revisions to classification of functional capacity and objective assessment of patients with diseases of the heart. 1994. Accessed March 23, 2011. Available at URL address: http://www.americanheart.org/presenter.jhtml?identifier=1712

4. Anderson JL, Adams CD, Antman EM, Bridges CR, Califf RM, Casey DE Jr, et al. American College of Cardiology; American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction); American College of Emergency Physicians; Society for Cardiovascular Angiography and Interventions; Society of Thoracic Surgeons; American Association of Cardiovascular and Pulmonary Rehabilitation; Society for Academic Emergency Medicine. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-Elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction) developed in collaboration with the American College of Emergency Physicians, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and the Society for Academic Emergency Medicine. J Am Coll Cardiol. 2007 Aug 14;50(7):e1-e157. No abstract available. Erratum in: J Am Coll Cardiol. 2008 Mar 4;51(9):974.

5. Arora RR, Chou TM, Jain D, Fleishman B, Crawford L, McKiernan T, et al. The multicenter study of enhanced external counterpulsation (MUST-EECP): effect of EECP on exercise-induced myocardial ischemia and anginal episodes. J Am Coll Cardiol. 1999;33(7):1833-40.

6. Barsness G, Feldman AM, Holmes DR, Holubkov R, Kelsey SF, Kennard ED. The International EECP Patient Registry (IEPR): design methods, baseline characteristics, and acute results. Clin Cardiol. 2001;24:435-42.

7. Bondesson S, Pettersson T, Erdling A, Hallberg IR, Wackenfors A, Edvinsson L. Comparison of patients undergoing enhanced external counterpulsation and spinal cord stimulation for refractory angina pectoris. Coron Artery Dis. 2008 Dec;19(8):627-34.

8. Braith RW, Conti CR, Nichols WW, Choi CY, Khuddus MA, Beck DT, Casey DP. Enhanced external counterpulsation improves peripheral artery flow-mediated dilation in patients with chronic angina: a randomized sham-controlled study. Vasc Med. 2010 Feb;15(1):15-20. Epub 2009 Oct 19.

9. Brosche TA, Middleton SK, Boogaard RG. Enhanced external counterpulsation. Dimensions of Critical Care Nursing. 2004;23(5):208-14.

10. Campbell AR, Satran D, Zenovich AG, Campbell KM, Espel JC, Arndt TL, et al. Enhanced external counterpulsation improves systolic blood pressure in patients with refractory angina. Am Heart J. 2008 Dec;156(6):1217-22. Epub 2008 Oct 5.

11. Canadian Cardiovascular Society (CCS). Grading of angina pectoris. 1976. Accessed March 23, 2011. Available at URL address: http://www.ccs.ca/position_statements/index_e.aspx

12. Cardiomedics. External counterpulsation technical guide. Copyright ©2005. Accessed March 23, 2011. Available at URL address: http://www.cardiomedics.com/

13. Centers for Medicare & Medicaid Services (CMS). NCD for External Counterpulsation (ECP) for Severe Angina (20.20). Effective March 20, 2006. Accessed March 23, 2011. Available at URL address: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd#PE

14. Centers for Medicare & Medicaid Services (CMS) Coverage issues manual, medical procedures: Decision Memo for External counterpulsation (ECP) Therapy (CAG-00002R2) March 20, 2006. Accessed March 23, 2011. Available at URL address: http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=162

15. Deer TR, Raso LJ. Spinal cord stimulation for refractory angina pectoris and peripheral vascular disease. Pain Physician. 2006 Oct;9(4):347-52.

16. ECRI Institute. External counterpulsation for the treatment of stable angina. [Emerging Technology evidence report]. Plymouth Meeting (PA): ECRI Institute; 2000 29 June]. Available at URL address: http://www.ecri.org

17. Eliasson T, Augustinsson LE, Mannheimer C. Spinal cord stimulation in severe angina pectoris: presentation of current studies, indications and clinical experience. Pain. 1996;65:169–79.

18. Erdling A, Bondesson S, Pettersson T, Edvinsson L. Enhanced external counter pulsation in treatment of refractory angina pectoris: two year outcome and baseline factors associated with treatment failure. BMC Cardiovasc Disord. 2008 Dec 18;8:39.

19. Feldman AM, Silver MA, Francis GS, De Lame PA, Parmley WW. Treating heart failure with enhanced external counterpulsation (EECP): design of the Prospective Evaluation of EECP in Heart Failure (PEECH) trial. J Card Fail. 2005 Apr;11(3):240-5.

20. Feldman AM, Silver MA, Francis GS, Abbottsmith CW, Fleishman BL, Soran O, et al: PEECH Investigators. Enhanced external counterpulsation improves exercise tolerance in patients with chronic heart failure. J Am Coll Cardiol. 2006 Sep 19;48(6):1198-205.

21. Fraker TD Jr, Fihn SD; 2002 Chronic Stable Angina Writing Committee; American College of Cardiology; American Heart Association, Gibbons RJ, Abrams J, Chatterjee K, Daley J, et al. 2007 chronic angina focused update of the ACC/AHA 2002 guidelines for the management of patients with chronic stable angina: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines Writing Group to develop the focused update of the 2002 guidelines for the management of patients with chronic stable angina. J Am Coll Cardiol. 2007 Dec 4;50(23):2264-74.

22. Gibbons RJ, Abrams J, Chatterjee K, Daley J, Deedwania PC, Douglas JS, et al.; American College of Cardiology (ACC); American Heart Association (AHA) Task Force on Practice Guidelines (Committee on the Management of Patients with Chronic Stable Angina). ACC/AHA 2002 guideline update for the

management of patients with chronic stable angina—summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2003 Jan 1;41(1):159-68.

23. Heart Failure Society of America (HFSA). The stages of heart failure – NYHA classification. Sept 29, 2006. Accessed March 24, 2011. Available at URL address: http://www.abouthf.org/questions_stages.htm

24. Holubkov R, Kennard ED, Foris JM, Kelsey SF, Soran O, Williams DO, et al. Comparison of patients undergoing enhanced external counterpulsation and percutaneous coronary intervention for stable angina pectoris. Am J Cardiol. 2002 May;89(10):1182-6.

25. Hunt SA; American College of Cardiology; American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). J Am Coll Cardiol. 2005 Sep 20;46(6):e1-82.

26. Lawson WE, Hui JCK, Zheng ZS. Three-year sustained benefit from enhanced external counterpulsation in chronic stable angina. Am J Cardiol. 1995;75(12):840-1.

27. Lawson WE, Hui JCK, Zheng ZS. Improved exercise tolerance following enhanced external counterpulsation: cardiac or peripheral effect? Cardiology. 1996a;87:271-5.

28. Lawson WE, Hui JCK, Zheng ZS. Can angiographic findings predict which coronary patients will benefit from enhanced external counterpulsation? Am J Cardiol. 1996b;77:1107-9.

29. Lawson WE, Hui JCK, Guo T, Burger L, Cohn PF. Prior revascularization increases the effectiveness of enhanced external counterpulsation. Clin Cardiol. 1998;21:841-4.

30. Lawson WE, Hui JCK, Cohn PF. Long-term prognosis of patients with angina treated with enhanced external counterpulsation: five-year follow-up study. Clin Cardiol. 2000a;23:254-8.

31. Lawson WE, Hui JCK, Lang G. Treatment benefit in the enhanced external counterpulsation consortium. Cardiology. 2000b;94:31-5.

32. Lawson WE, Kennard ED, Holubkov R, Kelsey SF, Strobeck JE, Soran O, et al. Benefit and safety of enhanced external counterpulsation in treating coronary artery disease patients with a history of congestive heart failure. Cardiology 2001;96(2):78-84.

33. Lawson WE, Silver MA, Hui JC, Kennard ED, Kelsey SF. Angina patients with diastolic versus systolic heart failure demonstrate comparable immediate and one-year benefit from enhanced external counterpulsation. J Card Fail. 2005 Feb;11(1):61-6.

34. Lawson WE, Hui JC, Kennard ED, Kelsey SF, Michaels AD, Soran O; International Enhanced External Counterpulsation Patient Registry Investigators. Two-year outcomes in patients with mild refractory angina treated with enhanced external counterpulsation. Clin Cardiol. 2006 Feb;29(2):69-73.

35. Lawson WE, Hui JC, Kennard ED, Soran O, McCullough PA, Kelsey SF; for the IEPR Investigators. Effect of enhanced external counterpulsation on medically refractory angina patients with erectile dysfunction. Int J Clin Pract. 2007 May;61(5):757-62.

36. Loh PH, Louis AA, Windram J, Rigby AS, Cook J, Hurren S. The immediate and long-term outcome of enhanced external counterpulsation in treatment of chronic stable refractory angina. J Intern Med. 2006 Mar;259(3):276-84.

37. Loh PH, Cleland JG, Louis AA, Kennard ED, Cook JF, Caplin JL, et al. Enhanced external counterpulsation in the treatment of chronic refractory angina: a long-term follow-up outcome from the International Enhanced External Counterpulsation Patient Registry. Clin Cardiol. 2008 Apr;31(4):159-64.

38. Manchanda A, Soran O. Enhanced external counterpulsation and future directions: step beyond medical management for patients with angina and heart failure. J Am Coll Cardiol. 2007 Oct 16;50(16):1523-31.

39. Mannheimer C, Camici P, Chester MR, Collins A, DeJongste M, Eliasson T, et al. The problem of chronic refractory angina; report from the ESC Joint Study Group on the Treatment of Refractory Angina. Eur Heart J. 2002 Mar;23(5):355-70.

40. McKenna C, McDaid C, Suekarran S, Hawkins N, Claxton K, Light K, et al. Enhanced external counterpulsation for the treatment of stable angina and heart failure: a systematic review and economic analysis. Health Technol Assess. 2009 Apr;13(24):iii-iv, ix-xi, 1-90.

41. Michaels AD, Accad M, Ports TA, Grossman W. Left ventricular systolic unloading and augmentation of intracoronary pressure and Doppler flow during enhanced external counterpulsation. Circulation. 2002;106:1237-42.

42. Michaels AD, Linnemeier G, Soran O, Kelsey S, Kennard E. Two-year outcomes after enhanced external counterpulsation for stable angina pectoris (from the International EECP Patient Registry [IEPR]). Am J Cardiol. 2004;93(4):461-8.

43. Michaels AD, Barsness GW, Soran O, Kelsey SF, Kennard ED, Hui JC, et al.; International EECP Patient Registry Investigators. Frequency and efficacy of repeat enhanced external counterpulsation for stable angina pectoris (from the International EECP Patient Registry). Am J Cardiol. 2005 Feb 1;95:94-7.

44. Michaels AD, Raisinghani A, Soran O, de Lame PA, Lemaire ML, Kligfield P, et al. The effects of enhanced external counterpulsation on myocardial perfusion in patients with stable angina: a multicenter radionuclide study. Am Heart J. 2005 Nov;150(5):1066-73.

45. Michaels AD, McCullough PA, Soran OZ, Lawson WE, Barsness GW, Henry TD, et al. Primer: practical approach to the selection of patients for and application of EECP. Nat Clin Pract Cardiovasc Med. 2006 Nov;3(11):623-32.

46. Morrow DA, Bodin WE. Enhanced external counterpulsation. In: Libby P, Bonow RO, Mann DL, Zipes DP, editors. Braunwald's Heart Disease. A Textbook of Cardiovascular Medicine. 9th ed. Philadelphia, PA: Saunders; 2011 Ch 57.

47. Nichols WW, Estrada JC, Braith RW, Owens K, Conti CR. Enhanced external counterpulsation treatment improves arterial wall properties and wave reflection characteristics in patients with refractory angina. J Am Coll Cardiol. 2006 Sep 19;48(6):1208-14.

48. Ochoa AB, deJong A, Grayson D, Franklin B, McCullough P. Effect of enhanced external counterpulsation on resting oxygen uptake in patients having previous coronary revascularization and in healthy volunteers. Am J Cardiol. 2006 Sep 1;98(5):613-5.

49. Pettersson T, Bondesson S, Cojocaru O, Wackenfors A, Edvinsson L. One year follow-up of patients with refractory angina pectoris treated with enhanced external counterpulsation. BMC Cardiovasc Disord. 2006 Jun 15;6:28.

50. Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB 3rd, et al.; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; ACC/AHA/SCAI Writing Committee to Update 2001 Guidelines for Percutaneous Coronary Intervention. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing

Committee to Update 2001 Guidelines for Percutaneous Coronary Intervention). Circulation. 2006 Feb 21;113(7):e166-286.

51. Snow V, Barry P, Fihn SD, Gibbons RJ, Owens DK, Williams SV, Mottur-Pilson C, Weiss KB; American College of Physicians; American College of Cardiology Chronic Stable Angina Panel. Primary care management of chronic stable angina and asymptomatic suspected or known coronary artery disease: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2004 Oct 5;141(7):562-7.

52. Soran O. A new treatment modality in heart failure enhanced external counterpulsation (EECP). Cardiol Rev. 2004 Jan-Feb;12(1):15-20.

53. Soran O, Kennard ED, Kfoury AG, Kelsey SF; IEPR Investigators. Two-year clinical outcomes after enhanced external counterpulsation (EECP) therapy in patients with refractory angina pectoris and left ventricular dysfunction (report from The International EECP Patient Registry). Am J Cardiol. 2006 Jan 1;97(1):17-20. Epub 2005 Nov 2.

54. Stys T, Lawson WE, Hui JC, Fleishman B, Manzo K, Strobeck JE, et al. Acute hemodynamic effects and angina improvement with enhanced external counterpulsation. Angiology. 2001;52(10):653-8.

55. Stys T, Lawson WE, Hui JC, Fleishman B, Manzo K, Strobeck JE, et al. Effects of enhanced external counterpulsation on stress radionuclide coronary perfusion and exercise capacity in chronic stable angina pectoris. Am J Cardiol. 2002;89(7):822-4.

56. Taguchi I, Ogawa K, Oida A, Abe S, Kaneko N, Sakio H. Comparison of hemodynamic effects of enhanced external counterpulsation and intra-aortic balloon pumping in patients with acute myocardial infarction. Am J Cardiol. 2000 Nov 15;86(10):1139-41, A9.

57. Taguchi I et al. Effects of enhanced external counterpulsation on hemodynamics and its mechanism. Circ J. 2004 Nov;68:1030-4.

58. Thakkar BV, Hirsch AT, Satran D, Bart BA, Barsness G, McCullough PA, et al. The efficacy and safety of enhanced external counterpulsation in patients with peripheral arterial disease. Vasc Med. 2010 Feb;15(1):15-20. Epub 2009 Oct 19.

59. United States Food and Drug Administration (FDA). 510(k) summary. Cardiassist external counterpulsation. K792430. Decision Date January 23, 1980. Accessed March 24, 2011. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K792430

60. Vasomedical, Inc. EECP. Patient selection. Accessed March 24, 2011. Available at URL address: http://www.eecp.com

61. Werner D, Michalk F, Harazny J, Hugo C, Daniel WG, Michelson G. Accelerated reperfusion of poorly perfused retinal areas in central retinal artery occlusion and branch retinal artery occlusion after a short treatment with enhanced external counterpulsation. Retina. 2004 Aug;24:541-7.

62. Werner D, Trägner P, Wawer A, Porst H, Daniel WG, Gross P. Enhanced external counterpulsation: a new technique to augment renal function in liver cirrhosis. Nephrol Dial Transplant. 2005 May;20(5):920-6. Epub 2005 Mar 23.

63. Xin W, Fangjian G, Hua W, Jiangtao X, Shouyi W, Yingchun Z, Xiong L. Enhanced external counterpulsation and traction therapy ameliorates rotational vertebral artery flow insufficiency resulting from cervical spondylosis. Spine (Phila Pa 1976). 2010 Jul 1;35(15):1415-22.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2008	0058	External Counterpulsation
Great-West Healthcare	8/23/2007	01.312.03	External Counterpulsation (ECP)