

# Cigna Medical Coverage Policy



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Subject **External Counterpulsation**

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## INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, 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 supersedes** 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. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

## 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

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## 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; ECRI, 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 (Cardiomedics, 2014; Vasomedical, 2012):

- abdominal aortic aneurysm
- 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
- peripheral vascular disease
- left ventricular hypertrophy
- severe pulmonary disease
- bleeding diathesis (coumadin therapy with PT/INR  $> 3.0$ )
- sustained arrhythmias
- arrhythmias that interfere with machine triggering
- active thrombophlebitis
- severe extremity vaso-occlusive disease
- pregnancy
- severe congestive heart failure
- burn, wound or fracture of any limb subject to treatment

Much of the published literature has evaluated ECP for cardiac-related conditions such as angina pectoris and congestive heart failure (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, 2014).

### **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 (β)-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], 2011; Gibbons, et al., 2003; American Heart Association [AHA], 1994; CCS, 1976).

**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; 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) 2011 update to the 2005 practice guideline for percutaneous coronary intervention does not mention ECP (Levine, et al, 2011).

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). There has been no update to this guideline since 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 focused update of the ACC/AHA 2002 guidelines for the management of patients with chronic stable angina (Fraker, et al., 2007). There has been no update to this guideline 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) (Lin, et al., 2012; 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  $\geq 60$  seconds on treadmill, absolute change [seconds]); peak volume of oxygen uptake ( $Vo_2$ ) (percentage of individuals with increase  $\geq 1.25$  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.

In a noncontrolled study, 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). The 2013 updated guideline does not mention ECP therapy (Yancy, et al., 2013).

### **Use Outside of the US**

ECP devices are available in several countries other than the United States; device availability, regulatory guidance, and criteria for coverage vary according to the available health service options for each country.

### **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 other indication including but not limited to 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

<b>New York Heart Association and Canadian Cardiovascular Society Functional Classifications Class</b>	<b>New York Heart Association Functional Classification</b>	<b>Canadian Cardiovascular Society Functional Classification</b>
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	Inability to carry on any physical activity without discomfort—

	present even at rest. If any physical activity is undertaken, discomfort is increased.	anginal syndrome may be present at rest.
(Heart Failure Society of America [HFSA], 2010; Gibbons, et al., 2003; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).		

## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

### Covered when medically necessary:

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

†**Note:** Covered when used to report external counterpulsation for medically necessary conditions outlined in coverage position.

HCPCS Codes	Description
G0166	External counterpulsation, per treatment session

\*Current Procedural Terminology (CPT<sup>®</sup>) © 2013 American Medical Association: Chicago, IL.

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- 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.
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