

## Medical Policy



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### Title: Enhanced External Counterpulsation (EECP)

#### Professional

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### DESCRIPTION

Enhanced external counterpulsation (EECP) is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. It has been studied primarily as a treatment for patients with refractory angina and heart failure.

#### Background

Enhanced external counterpulsation (EECP) uses timed, sequential inflation of pressure cuffs on the calves, thighs, and buttocks to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. Augmenting diastolic pressure displaces a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and the resistance in the coronary arteries is at a minimum. The resulting increase in coronary artery perfusion pressure may enhance coronary collateral development or increase flow through existing collaterals. In

addition, when the left ventricle contracts, it faces a reduced aortic pressure to work against, since the counterpulsation has somewhat emptied the aorta. EECP has been primarily investigated as a treatment for chronic stable angina.

Intra-aortic balloon counterpulsation is a more familiar, invasive form of counterpulsation that is used as a method of temporary circulatory assistance for the ischemic heart, often after an acute myocardial infarction (MI). In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the development of coronary collateral development. A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms (EKGs) to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

### Regulatory Status

While EECP has been primarily researched as a treatment of chronic stable angina, it has also been used in patients with heart failure. The Vasomedical EECP® Therapy System Model has the following labeled indication under 510(k) clearance from the U.S. Food and Drug Administration (FDA):

"The EECP Therapy System Model TS3 with Pulse Oximetry is a non-invasive external counterpulsation device intended for the use in the treatment of patients with heart failure, stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock."

Cardiomedics, Inc. has FDA 510(k) clearance to market the CardiAssist Counterpulsation System (K022107) and the CardiAssist ECP System (K010261) for the same indications as the Vasomedical EECP® systems.

### POLICY

- A. EECP is considered **medically necessary** for patients meeting the following criteria:
  - 1. for patients with disabling angina (New York Heart Association class III or IV); and
  - 2. refractory to maximum medical therapy (maximum doses of nitrates, beta blockers, and calcium blockers); and
  - 3. not amenable to surgical intervention
- B. EECP should not be allowed for patients with congestive heart failure.

**UTILIZATION**

1. Any request for repeat EECp must be reviewed.
2. The EKG (ECG), oximetry and plethysmography are all content of service if done on the same day.
3. Up to 35 treatment sessions will be allowed. Any treatment sessions over 35 will be reviewed.

**RATIONALE**

Randomized controlled trials (RCTs) that report on relevant clinical outcomes are required to determine whether enhanced external counterpulsation (EECP) is efficacious and whether it is at least as good as alternative treatments. Observational data are of limited utility given the variable natural history of disorders such as angina and/or heart failure, the presence of many potential confounders of cardiac outcomes, and the potential for a placebo effect.

**Literature Review**

The literature base consists of a small number of RCTs, some of which report relevant clinical outcomes and others that report intermediate, or physiologic, outcome measures. In addition to the small number of RCTs, there are a large number of observational studies, including publications from EECp registries and case series, which generally report pre- and post-treatment measures of EECp effectiveness.

**Chronic Stable Angina**

The original literature review for this policy was based on a 1999 TEC Assessment on enhanced external counterpulsation (EECP) for chronic stable angina and updated with 2002 and 2005 TEC Assessments. These assessments concluded that the evidence was insufficient to determine whether EECp improved the net health outcome or is as beneficial as any established alternatives in patients with chronic stable angina.

Specifically, the 2005 TEC Assessment offered the following observations and conclusions regarding EECp for chronic stable angina (1):

- There is insufficient evidence to draw conclusions about the benefits of EECp.
- The results of the single randomized, controlled trial, the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP), discussed further here, must be interpreted with caution, in view of the high subject dropout rate and uncertainty regarding the clinical significance of the reported improvement in physiologic measures, especially when intent-to-treat analysis is applied. (2, 3)
- Comparative studies of EECp do not address the hard outcomes of cardiac death or recurrent cardiac events such as myocardial infarction and revascularization procedures. (4, 5)

- Several case series and registry-based studies have reported the outcomes of large numbers of patients treated in a number of different institutions. There are several problems with this kind of evidence. These studies, while contributing to the body of knowledge of EECp, do little to address the efficacy or durability of EECp treatment. The lack of comparison groups makes it impossible to rule out either placebo effect or spontaneous recovery among patients with milder disease.

In 1999, Arora and colleagues presented results of the MUST-EECP trial. MUST-EECP applied a randomized, controlled, double-blinded protocol that compared active treatment to placebo (inactive counterpulsation [CP] sham treatment) among 139 patients with Canadian Cardiovascular Society (CCS) Classification Scales (a functional assessment tool based on the level of exertion that elicits symptoms) class I–III chronic, stable angina. (2) Four outcomes were examined:

- Self-reported frequency of angina, analyzed two ways;
- Self-reported use of on-demand nitroglycerin;
- Exercise duration tolerance testing; and
- Time to exercise-induced ischemia (defined as time to depression of  $\geq 1$  mm in the ST segment on electrocardiogram).

All patients underwent the same 35-hour protocol, followed by an exercise tolerance test within 1 week of completion of therapy. Follow-up beyond the treatment period was not conducted.

Intention-to-treat analyses were reported for the angina count and nitroglycerin usage outcomes only. There was a statistically significant difference ( $p=0.01$ ) between groups in the change in time to  $\geq 1$  mm ST segment depression. Patients in the EECp group had an average difference of 37 seconds longer time to ST segment depression compared to the sham-treated group. There was no significant difference between treatment groups in the change in exercise duration from baseline to the post-treatment period ( $p<0.31$ ). In addition, there were no statistically significant differences between groups with respect to angina counts ( $p<0.09$ ) or nitroglycerin use ( $p>0.1$ ).

In addition to a number of methodologic limitations found in the design, execution, and reporting of this study, the magnitude of the benefit reported is not large. Of the 4 endpoints of interest, only the time to ST segment depression was statistically different in the EECp group compared to the sham-treated group. The clinical significance of a 37-second improvement in time to ST segment depression is unknown, but given that it occurred while the other 3 endpoints were statistically unchanged with therapy, does not suggest a marked improvement. That both groups showed increased exercise duration suggests a degree of placebo effect; exercise duration possesses a motivational component that time to ST segment depression does not.

In 2002, Arora and colleagues published a 12-month follow-up study to the MUST-EECP trial. (3) However, only 71 (54%) of the original 139 subjects were included in the study. Subjects treated with EECP reported greater improvement in several quality-of-life scales. However, such findings could not be correlated with treatment response reported in the first study (because of data limitations). The findings are further limited by the small sample size and potentially biased sample of the original subject pool.

Some small RCTs have reported on intermediate, or physiologic, outcomes. One such RCT (n=20) was published in 2010 comparing intracoronary blood flows in patients treated with EECP against those treated with a sham procedure. (6) This trial was designed to detect statistically significant differences in collateral flow rates by angiography, not anginal symptoms. After 7 weeks of treatment, collateral flow index increased significantly in the EECP group compared to sham treatment. Similar findings were noted in a comparative study by Buschmann and colleagues of 23 patients published in 2009. (7)

Two publications from a single study reported on blood flow and other measures of arterial function. (8, 9). This study randomized 42 patients with coronary artery disease (CAD) and chronic angina to EECP or sham EECP. EECP improved flow-mediated dilation in the brachial and femoral arteries and improved numerous serum markers of blood flow and inflammation. The same study also reported that measures of arterial stiffness were improved in the EECP group. Martin et al. (10) randomized 18 patients with abnormal glucose tolerance to EECP or standard care and reported that measures of glucose tolerance, as well as measures of arterial function were improved in the EECP group.

A number of systematic reviews of the literature have been performed evaluating EECP for chronic stable angina. In 2010, Amin and colleagues published a Cochrane review of major databases through 2008 on evidence of the effectiveness of EECP for chronic angina pectoris. (11) The solitary RCT identified was the MUST-EECP trial. The authors of this review highlighted patient selection for this study. They comment that limiting the study population to patients with CCS class below IV diminishes the study's generalizability to patients of interest, that is, patients with the most severe symptoms of chronic angina pectoris.

Also in 2010, Shah and colleagues published a meta-analysis of prospective studies, not limited to RCTs, of EECP in stable angina in which CCS class was adequately reported before and after treatment. (12) The MUST-EECP RCT was not included, as change in CCS class was not one of the reported outcomes. A total of 13 studies met these inclusion criteria (n=949 patients). Overall, improvement of at least 1 level of angina class occurred in 86% of patients (95% confidence interval [CI]: 82-90%, p=0.008). No conclusions can be drawn from this analysis given the lack of randomization (comparison group) for most studies in this analysis.

In a 2009 paper, McKenna and colleagues report on a systematic review and economic analysis of EECP for the treatment of stable angina and heart failure. (13) Four studies (1 RCT and 3 non-randomized comparative studies) comparing EECP treatment with no treatment in adults with chronic stable angina were included in the analysis. (2-5) The systematic review included a study by Barsheshet and colleagues in which 25 patients (15 EECP and 10 controls) were evaluated at the end of treatment. (14) Similar to the previously reviewed Schechter et al. study, (5) "CCS classification improved with EECP but not with usual care, however statistical analysis of between group differences was not reported and, for CCS classification, the data were treated as continuous data which is inappropriate for this four-category classification."

Registry-based studies have been published that report on relatively large numbers of patients. In a registry-based study, 450 patients with left ventricular dysfunction (ejection fraction, EF  $\leq 40$ ) and refractory angina had 0.7 fewer emergency department visits and 0.8 fewer hospitalizations 6 months after treatment with EECP compared to the 6 months before EECP; 6-month data were available on only 81 patients. (15) Drawing conclusions from this study is not possible due to lack of a comparison group.

Another registry-based study (the International Enhanced External Counterpulsation Patient [IECP] Registry) reported long-term (3-year) results on patients with chronic refractory angina for patients in this registry. (16) The registry enrolled 5,000 patients from 99 U.S. and 9 international centers between 1999 and 2001. However, analysis was completed only for those centers that had at least 80% compliance with follow-up data submission; the study reported results on 1,427 patients. In this selective group, 220 patients (15.4%) died, while 1,061 patients (74.4%) completed their follow-up. Immediately post-EECP, the proportion of patients with severe angina (Canadian Cardiovascular Angina Classification [CCS] III/IV) were reduced from 89% to 25%,  $p < 0.001$ . This was sustained in 74% of the patients during follow-up. More severe baseline angina and a history of heart failure or diabetes were independent predictors of unfavorable outcome. Again, the lack of a control group precludes drawing conclusions about this technology based on this study.

The IECP data have also been examined to determine the safety and efficacy of the use of this device in patients with peripheral arterial disease. Peripheral arterial disease, while a common comorbidity of coronary artery disease, has been regarded as a relative contraindication to EECP due to concerns of compression on peripheral blood flow and a potentially greater risk of aortic rupture. Thakker and colleagues compared registry data in patients with peripheral arterial disease to those who did not. (17) Based on a reduction of one or more CCS angina classes, patients with peripheral arterial disease had a similar rate (76.6% vs. 79.0%, respectively;  $p = 0.27$ ) of improvement as did the group without peripheral arterial disease. Rates of hospitalization for all cardiac causes (6.1% vs. 4.4%, respectively;  $p = 0.17$ ) and for unstable angina (5.4% vs. 3.5%, respectively;  $p = 0.25$ ) were also similar between groups.

Numerous individual observational studies have been detailed in previous reviews and are included in systematic reviews described above. (3-5, 7, 14, 18) For example, 2 prospective cohort studies (n=55 and n=61) with 1-year outcomes have been reported. (19, 20) Improved CCS classification was the main reported outcome, which persisted for 1 year in 79% and 78% of patients in the respective studies. Both studies had higher rates of treatment completion and follow-up than the previously reported (registry) studies of long-term outcomes. These studies address the need for data regarding treatment durability, but their single-arm design does not change policy conclusions.

In summary, the data for use of EECP in chronic stable angina are insufficient to form conclusions on the efficacy of this treatment. The single randomized trial (MUST-EECP) that included relevant clinical outcomes reported a benefit on 1 of 4 main angina-related outcomes, and the magnitude of this benefit was of uncertain clinical significance. The RCTs that report on intermediate outcomes offer evidence on possible physiologic mechanisms underlying EECP treatment but do not themselves provide evidence of health outcome benefits. Observational studies, such as registry data and case series, offer little evidence on the efficacy of this procedure due to the variable natural history of angina, the multiple confounders of cardiac outcomes, and the potential for a placebo effect.

#### Heart Failure

The 510(k) approval of the Vasomedical devices states that objective measures such as peak oxygen consumption, exercise duration, and pre-load-adjusted maximal left ventricular power are improved following EECP therapy, as well as subjective measures of patient response to therapy, such as quality of life and functional ability measures. (21) However, no clinical details of these studies are provided in the FDA summary, and these data are not from controlled trials.

The 2005 TEC Assessment (1) included heart failure in the analysis and concluded the evidence supporting the role of EECP as an effective treatment for heart failure is lacking in both quantity and quality. A single randomized, multicenter study of EECP compared to usual care in 187 optimally medically managed patients with New York Heart Association (NYHA) functional class II/III heart failure with EF  $\leq$ 35% of ischemic or idiopathic etiology, the "Prospective Evaluation of EECP in Congestive Heart Failure" (PEECH trial), was mostly inconclusive. (22) The design and methods of the PEECH trial were published by Feldman and colleagues. (23) The results of the PEECH trial found statistically improved, but modest, changes in exercise duration and improved functional classification but not in quality of life or peak oxygen uptake. (22)

A subgroup analysis from the PEECH trial for CHF was published. (24) It showed that subjects aged 65 years and older treated with EECP (n=41) were more likely to meet the exercise duration (35% vs. 25% increased by  $\geq$ 60 seconds) and peak VO<sub>2</sub> (30% vs. 11% increased by  $\geq$ 1.25 ml/kg per min) improvement thresholds compared to those

undergoing sham treatment (n=45); there was no difference at 6 months in NYHA class. This post-study analysis must be viewed as a preliminary result.

Registry studies for heart failure use angina outcomes and contribute little to the body of evidence. (25-28) The single-arm study by Soran et al. (29) indicates that patients respond with some improvements, but the lack of a comparison arm precludes inference about the true effects of therapy. Treatment durability for either angina or heart failure has yet to be addressed with long-term studies. Therefore, the evidence is insufficient to determine whether EECp improves the net health outcome or is as beneficial as any established alternatives in patients with chronic stable heart failure.

The previously described 2009 review by McKenna and colleagues (13) included the single trial of EECp for heart failure included in the systematic review, the PEECH study. (22) The authors conclude that the studies do not provide firm evidence of the clinical effectiveness of EECp in refractory stable angina or in heart failure and that high quality studies are required to investigate the benefits of EECp and whether these outweigh the common adverse effects.

In summary, evidence for the use of EECp in heart failure is insufficient to form conclusions on efficacy. The single RCT that includes clinical outcomes reported modest improvements on some outcomes and no improvement on others. The observational studies add little to the evaluation of efficacy due to the variable natural history of heart failure, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect. Further high-quality RCTs are needed to determine whether EECp is a useful treatment for heart failure.

### Other Indications

The use of EECp for other conditions of ischemia has been investigated. In 2009, Fraser and Adams produced a Cochrane review on interventions for central retinal artery occlusion (CRAO). (30) One of the 2 RCTs identified compared hemodilution with EECp against hemodilution without further intervention. In this case, the EECp intervention was a single, 2-hour treatment. According to the reviewers, in this study (n=20), patients were randomized but not blinded; no sham treatment was given. Primary outcomes were Doppler flowmetry of retinal perfusion and visual acuity. (31) While acknowledging the relative safety of the technique, the authors remark, "The small size of the stud[y], potential for bias and the lack of data on final vision means that we do not have convincing evidence at present to support the routine use of...EECP in patients with CRAO."

Published registry studies also demonstrated improvements in erectile function. (32) Erectile function was improved in a study of 120 men prospectively enrolled from 16 centers. Three of 5 domains of the International Index of Erectile Function were statistically improved with EECp treatment (erectile function, intercourse satisfaction, and overall satisfaction), and the total score improved from 28 to 32, a statistically significant improvement. (32) The non-comparative design of this study makes it

difficult to draw conclusions on treatment efficacy. This indication is added as investigational due to lack of adequate data on clinical outcomes. Preliminary studies from Asia are also reporting early results on use of EECP to the lower extremities in the treatment of acute ischemic stroke. (33) However, these small, uncontrolled trials are considered early results, and this indication is added as investigational due to lack of data concerning impact on outcomes.

### Summary

The evidence on the efficacy of EECP for treatment of chronic angina is insufficient to form conclusions. There is only one RCT that includes clinical outcomes, and this trial reported benefit on only 1 of 4 main angina outcomes. Additional small RCTs report changes in physiologic measures associated with EECP but do not provide relevant evidence on clinical efficacy. The evidence from observational studies, including registry studies with large numbers of patients, add little to determinations of efficacy. This is because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect.

For the treatment of heart failure, the evidence is of a similar nature. There is one RCT that includes clinical outcomes, and this trial reports modest benefits on some outcomes and no benefit on others. The observational studies on EECP in heart failure have the same limitations as do the studies on chronic angina. There is very limited evidence on the use of EECP for indications other than chronic angina or heart failure. For these reasons, the use of EECP is considered investigational for all indications.

### Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received from 3 academic medical centers while this policy was under review, 1 during review in April 2008, 1 during review in October 2008, and 1 during review in 2009. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. Reviewers agreed with the conclusion that this was investigational. Some reviewers commented about potential use in those with angina not amenable to surgical interventions.

### Practice Guidelines and Position Statements

The 2002 American College of Cardiology/American Heart Association (ACC/AHA) guidelines on the management of patients with chronic stable angina state that the available evidence is insufficient to recommend EECP and call for additional clinical data. (34) A focused 2007 update does not alter that recommendation. (35)

**CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

**CPT/HCPCS**

92971 Cardioassist-method of circulatory assist; external  
 G0166 External counterpulsation, per treatment session

**DIAGNOSIS**

**These diagnoses are otherwise subject to medical policy as stated above**

413.0 Angina decubitus  
 413.1 Prinzmetal angina  
 413.9 Other and unspecified angina pectoris

**ICD-10 Diagnosis (Effective October 1, 2014)**

I20.1 Angina pectoris with documented spasm  
 I20.8 Other forms of angina pectoris  
 I20.9 Angina pectoris, unspecified  
 I25.111 Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm  
 I25.118 Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris  
 I25.119 Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris  
 I25.701 Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm  
 I25.708 Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris  
 I25.709 Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris  
 I25.711 Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm  
 I25.718 Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris  
 I25.719 Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris  
 I25.721 Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm  
 I25.728 Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris  
 I25.729 Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris  
 I25.731 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm

- I25.738 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
- I25.739 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
- I25.751 Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
- I25.758 Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris
- I25.759 Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
- I25.761 Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
- I25.768 Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
- I25.769 Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
- I25.791 Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
- I25.798 Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
- I25.799 Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris

## REVISIONS

Effective 09-21-2005	<ul style="list-style-type: none"> <li>• Liberalized from experimental / investigational to medically necessary for disabling angina (New York Heart Association class III or IV), and refractory to maximum medical therapy, and not amenable to surgical intervention, per Medical Director.</li> </ul>
Effective 11-01-2007	<ul style="list-style-type: none"> <li>• Policy clarified by adding, "Any request for repeat EECP must be reviewed."</li> <li>• References were updated.</li> </ul>
06-26-2013	Updated the Description section.
	Added Medical Policy and Coding Disclaimers.
	In Policy section: <ul style="list-style-type: none"> <li>▪ In the Utilization section, removed #2, "An office visit will be allowed in addition to G0166 and 92971."</li> <li>▪ Moved statement, "Any request for repeat EECP must be reviewed." to the Utilization section.</li> </ul>
	Added the Rationale section.
	Updated and formatted the Reference section.
02-05-2014	In Coding section: <ul style="list-style-type: none"> <li>▪ Added ICD-10 Diagnosis (<i>Effective October 1, 2014</i>)</li> </ul>

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