Medical Policy

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Title: Enhanced External Counterpulsation (EECP)

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Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic stable angina	Interventions of interest are: • Enhanced external counterpulsation	Comparators of interest are: • Medical management	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Functional outcomes
Individuals: • With heart failure	Interventions of interest are: • Enhanced external counterpulsation	Comparators of interest are: • Guideline-directed medical management	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Functional outcomes

Populations	Interventions	Comparators	Outcomes
Individuals: • With other conditions related to ischemia or vascular dysfunction	Interventions of interest are: • Enhanced external counterpulsation	Comparators of interest are: • Guideline-directed medical management	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Functional outcomes

DESCRIPTION

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

OBJECTIVE

The objective of this evidence review is to determine whether the use of enhanced external counterpulsation improves the net health outcome in individuals who have chronic stable angina, heart failure, or other cardiovascular conditions.

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. The proposed mechanism of action is the augmentation of diastolic pressure by displacement of a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and 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. Also, when the left ventricular contracts, it faces reduced aortic counterpressure, because 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 acute myocardial infarction. In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the 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 a week. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

REGULATORY STATUS

A variety of EECP devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of EECP devices with FDA clearance are outlined in Table 1. FDA product code: DRN.

Table 1. FDA-Cleared EECP Devices

Device	Manufacturer	Cleared	Indications
External Counterpulsation System	Vamed Medical Instrument	Sep 2019	• Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization • In healthy patients to improve vasodilation, increase Vo2, and increase blood flow
Pure Flow External Counter-Pulsation Device	Xtreem Pulse	May 2018	• Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization • In healthy patients to improve vasodilation, increase Vo2, and increase blood flow
Renew® NCP-5 External Counterpulsation System	Renew Group	Dec 2015	• Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization • In healthy patients to improve vasodilation, increase Vo2, and increase blood flow
ECP Health System Model	ECP Health	Aug 2005	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive heart failure
CardiAssist™ Counter Pulsation System	Cardiomedics	Mar 2005	• Ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction, and cardiogenic shock
ACS Model NCP-2 External Counterpulsation Device	Applied Cardiac Systems	Aug 2004	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive heart failure
EECP® Therapy System	Vasomedical	Mar 2004	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive heart failure

EECP: enhanced external counterpulsation; FDA: Food and Drug Administration; Vo2: oxygen consumption.

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.

Policy Guidelines

This policy only addresses the outpatient uses of enhanced external counterpulsation (EECP), ie, for the treatment of chronic stable angina or heart failure. This policy does not address its use for unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 11, 2021.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

CHRONIC STABLE ANGINA

Clinical Context and Therapy Purpose

The purpose of enhanced external counterpulsation (EECP) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as guideline-directed medical management, in patients with chronic stable angina.

The question addressed in this evidence review is: Does the use of EECP improve the net health outcome in individuals with chronic stable angina?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic stable angina.

Interventions

The therapy being considered is EECP. EECP is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return.

Comparators

Comparators of interest include guideline-directed medical management.

Outcomes

The general outcomes of interest are overall survival (OS), symptoms, morbid events, and functional outcomes.

Available literature has followed patients for up to 3 years.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

The literature base consists of a low number of RCTs, some of which have reported relevant clinical outcomes, and others that have reported intermediate or physiologic outcome measures. Also, there are a large number of observational studies, including publications from EECP registries and case series, that have generally reported pretreatment and posttreatment measures of EECP effectiveness.

REVIEW OF EVIDENCE

Randomized Controlled Trials

Arora et al (1999) presented results of the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP) trial.[1,]The MUST-EECP trial applied a randomized controlled, double-blinded protocol that compared active treatment with placebo (inactive counterpulsation

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, II, or III chronic, stable angina. Four outcomes were examined: (1) self-reported frequency of angina, analyzed 2 ways; (2) self-reported use of on-demand nitroglycerin; (3) exercise duration tolerance testing; and (4) time to exercise-induced ischemia (defined as time to depression of ≥ 1 mm in the ST segment on an electrocardiogram).

All patients underwent the same 35-hour protocol, followed by an exercise tolerance test within 1 week of completing 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 =.01) between groups in the change in time to ≥ 1 mm or greater ST-segment depression. Patients in the EECP group had an average difference of 37 seconds longer time to ST-segment depression than the sham-treated group. There was no significant difference between treatment groups in the change in exercise duration from baseline to the posttreatment period (P <.31). Also, there were no statistically significant differences between groups concerning angina counts (P <.09) or nitroglycerin use (P >.1).

In addition to methodologic limitations found in the design, execution, and reporting of this trial, the magnitude of the benefit reported was not large. Of the 4 endpoints of interest, only time to ST-segment depression differed statistically in the EECP group compared with the sham group. The clinical significance of a 37-second improvement in time to ST-segment depression is unknown, but because it occurred while the other 3 endpoints were statistically unchanged with therapy should not suggest that this anomaly marks 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.

Arora et al (2002) published a 12-month follow-up to the MUST-EECP trial.[2,] Only 71 (54%) of the original 139 subjects 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 responses reported in the first study (because of data limitations). The findings were further limited by the small sample size and a potentially biased sample of the original subject pool.

Bondesson et al (2011) published a small unblinded RCT that addressed a single health outcome (change after 7 weeks in CCS angina class), along with multiple intermediate outcomes.[3,] Twenty patients with refractory angina (CCS class III) were randomized to EECP or no EECP. Mean CCS class was significantly improved in the EECP group but not in the no-EECP group. At the 7-week follow-up, soluble interleukin-2 receptor (a potential indicator of lymphocyte activation in atherosclerosis) measurements significantly increased in the EECP group and significantly decreased in the no-EECP group. There were no differences between groups at 7 weeks in resting cutaneous microvascular blood flow or response to acetylcholine, sodium nitroprusside, or local heating.

Additional RCTs have reported on intermediate, or physiologic, outcomes. Gloekler et al (2010) published one such RCT (N = 20), which compared intracoronary blood flows in patients treated using EECP with those treated using a sham procedure.[4,] 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 with sham treatment. Buschman et al (2009) noted similar findings in a comparative study et al (2009) of 23 patients.[5,]

Two publications reported on a single trial evaluating blood flow and other measures of arterial function.[6,7,] This trial randomized 42 patients with coronary artery disease 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 trial also reported that measures of arterial stiffness were improved in the EECP group.

Shakouri et al (2015), in a randomized pilot study, reported on intermediate outcome measures, including plasma nitric oxide, endothelin 1, and high-sensitivity C-reactive protein levels, as well as quality of life, in patients with coronary artery disease allocated to 20 sessions of EECP (n = 21) or cardiac rehabilitation (n = 21).[8,] There were no statistically significant improvements in the physiologic markers and quality of life over time in either group and no statistically significant between-group differences in change in any of the parameters evaluated.

Systematic Reviews

This evidence review was informed by a TEC Assessment (1999) on EECP for chronic stable angina, which was updated in 2002 and again in 2005.[9,] These Assessments concluded that the evidence was insufficient to determine whether EECP improved the net health outcome or was as beneficial as any established alternatives in patients with chronic stable angina.

Specifically, the 2005 Assessment offered the following observations and conclusions regarding EECP for chronic stable angina[9,]:

- The results of the single RCT, the MUST-EECP trial, must be interpreted with caution given the following factors: (1) the high subject dropout rate; and (2) the uncertain clinical significance of the reported improvement in physiologic measures, especially when intention-to-treat analysis was applied.[1,2,]
- Comparative studies of EECP did not address the hard outcomes of cardiac death or recurrent cardiac events, such as myocardial infarction and revascularization procedures.[10,11,]
- Several case series and registry-based studies have reported the outcomes of large numbers of patients treated in a number of different institutions. There were several problems with this kind of evidence:(1) these studies, while contributing to the body of knowledge of EECP, did little to address the efficacy or durability of EECP treatment; and (2) the lack of comparison groups made it impossible to rule out either placebo effect or spontaneous recovery among patients with milder disease.

Other systematic reviews have evaluated EECP for chronic stable angina. Amin et al (2010) published a Cochrane review of major databases through 2008 evaluating evidence of the effectiveness of EECP for chronic angina pectoris.[12,] The solitary RCT identified was the MUST-EECP trial. Reviewers highlighted patient selection for this trial. They noted that limiting the study population to patients with CCS class below IV diminished the trial's generalizability to patients of interest, i.e., patients with the most severe symptoms of chronic angina pectoris.

Shah et al (2010) 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.[13,] The MUST-EECP RCT was not included because the change in CCS class was not a reported outcome. Thirteen studies met these inclusion criteria (total N=949 patients). Overall,

improvement of at least 1 level of angina class occurred in 86% of patients (95% CI, 82% to 90%; *P* =.008). No conclusions can be drawn from this analysis given the lack of randomization (comparison group) for most studies analyzed.

McKenna et al (2009) reported on a systematic review and economic analysis of EECP for the treatment of stable angina and heart failure.[14,] Four studies (1 RCT, 3 nonrandomized comparative studies) comparing EECP treatment with no treatment in adults with chronic stable angina were selected.[1,2,10,11,]Barsheshet et al (2008) was also included in the systematic review for their study2008 in which 25 patients (15 EECP, 10 controls) were evaluated at the end of treatment.[15,] Similar to the Schechter et al (2003) study,[11,] "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."

Qin et al (2016) published a systematic review and meta-analysis (2016) that focused on the effect of EECP on the intermediate measure of myocardial perfusion in patients with coronary artery disease.[16,] Reviewers included 6 studies reporting on myocardial perfusion or coronary flow outcomes published from 1992 to 2007, including 5 RCTs and 1 prospective, observational, blinded study. In the pooled analysis, EECP was associated with increased myocardial perfusion in patients with coronary artery disease (pooled weighted mean difference = -0.19; 95% CI, -0.38 to 0.00; *P* =.049).

Registry Studies

Registry-based studies have reported on relatively large numbers of patients. Soran et al (2007)conducted a study on 450 patients with left ventricular dysfunction (ejection fraction, ≤ 40%) and refractory angina had 0.7 fewer emergency department visits and 0.8 fewer hospitalizations 6 months after treatment with EECP compared with the 6 months before EECP; 6-month data were available on only 81 patients.[17,] Drawing conclusions from this study is not possible due to lack of a comparison group.

Loh et al (2008) reported on another study from the International Enhanced External Counterpulsation Patient Registry (2008), providing 3-year results for patients with chronic refractory angina.[18,] The registry enrolled 5000 patients from 99 U.S. and 9 international centers between 1999 and 2001. However, this analysis was completed only for those centers that had at least 80% compliance with follow-up data submission; the study reported results on 1427 patients. In this select group, 220 (15.4%) patients died, while 1061 (74.4%) patients completed their follow-up. Immediately post-EECP, the proportion of patients with severe angina (CCS class III or IV) was reduced from 89% to 25% (*P*<.001). This improvement 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 in this study precludes drawing conclusions about this technology.

The International Enhanced External Counterpulsation Patient Registry data have also been examined to determine the safety and efficacy of EECP in patients with peripheral arterial disease (PAD). PAD, while a common comorbidity of coronary artery disease, has been regarded as a contraindication to EECP due to concerns about compression on peripheral blood flow and a potentially greater risk of aortic rupture. Thakkar et al (2010) compared registry data in patients who had PAD with those who did not.[19,] Based on a reduction of 1 or more CCS angina classes, patients with PAD had a similar rate of improvement as did the group without

PAD (76.6% vs. 79.0%, respectively; *P*=.27). Rates of hospitalization for all cardiac causes (6.1% vs. 4.4%, respectively; *P*=.17) and for unstable angina (5.4% vs. 3.5%, respectively; *P*=.25) were also similar between groups.

Observational Studies
Numerous individual observational studies have been detailed above and are included in systematic reviews previously described[2,5,10,11,15,20,] For example, 2 prospective cohort studies (N = 55 and N = 61) with 1-year outcomes have been reported.[21,22,] Improved CCS classification was the main reported outcome, which was maintained 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 assessing long-term outcomes.

Section Summary: Chronic Stable Angina
Data on use of EECP in chronic stable angina are insufficient to form conclusions about 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. RCTs that have reported on intermediate outcomes offer evidence on possible physiologic mechanisms underlying EECP treatment but do not themselves provide evidence of health outcome benefits. Observational studies (e.g., registry data, 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

Clinical Context and Therapy Purpose
The purpose of EECP is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as guideline-directed medical management, in patients with heart failure.

The question addressed in this evidence review is: Does the use of EECP improve the net health outcome in individuals with heart failure?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with heart failure.

Interventions
The therapy being considered is EECP. EECP is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return.

Comparators
Comparators of interest include guideline-directed medical management.

Outcomes
The general outcomes of interest are OS, symptoms, morbid events, and functional outcomes.

The limited available literature has followed patients for up to 6 months.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
The 510(k) approval of the Vasomedical devices stated that objective measures, such as peak oxygen consumption, exercise duration, and preload-adjusted maximal left ventricular power, are improved following EECP therapy, as are subjective measures of patient response to therapy, such as quality of life and functional ability.[23,] However, no clinical details of these studies were provided in the U.S. Food and Drug Administration (FDA) summary, and these data were not from controlled trials.

The 2005 TEC Assessment included heart failure in its analysis and concluded the evidence supporting the role of EECP as an effective treatment for heart failure was lacking in both quantity and quality.[9,] A single randomized, multicenter study has compared EECP with usual care in 187 optimally medically managed patients with New York Heart Association (NYHA) functional class II or III heart failure who had an ejection fraction of 35% or less of ischemic or idiopathic etiology.[24,] This study, the Prospective Evaluation of EECP in Congestive Heart Failure (PEECH trial), was mostly inconclusive. Feldman et al (2005) published the trial design and methodology by Feldman et al (2005).[23,]Feldman et al (2006) also reported on the PEECH trial results, (2006), indicating statistically improved, but modest, changes in exercise duration and improved functional class but not in quality of life or peak oxygen consumption.[24,]

A 2006 subgroup analysis of the PEECH trial 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 ≥ 60 seconds) and peak oxygen consumption (30% vs. 11% increased by ≥ 1.25 mL/kg/min) improvement thresholds compared with those undergoing sham treatment (n = 45); there was no difference at 6 months in NYHA class.[25,]

Rampengan et al (2015) reported on a double-blinded RCT evaluating EECP in patients with congestive heart failure treated in Indonesia.[26,] Patients with NYHA functional class I or II symptomatic heart failure of various causes were included. Patients were randomized to active EECP (n = 56) or sham EECP (n = 56), which involved the use of the EECP device at only 77 mm Hg of pressure versus the standard 300 mm Hg. The analysis was per protocol, excluding 6 and 7 patients who dropped out of the active and sham groups, respectively. Postintervention, active EECP group patients were more likely to have a 6-minute walk distance of 300 meters or greater (98.0% vs. 32.7%; *P*<.01). The change in 6-minute walk distance was greater (improved) for the active EECP patients (192.6 meters) than for the sham control patients (–9 meters; *P*<.05).

Similar to the registry evidence for EECP for angina, registry studies for heart failure have provided relatively little insight into the comparative efficacy of EECP.[27,28,29,30,] Soran et al (2002)

conducted a single-arm study indicating that patients showed some improvements, but the lack of a comparison arm precluded inferences about the true effects of therapy.[31,]

McKenna et al (2009), in their previously described review,[14,] included the only trial of EECP for heart failure available at that time, the 2006 PEECH study.[24,] Reviewers concluded that the studies did not provide firm evidence of the clinical effectiveness of EECP in heart failure and that high-quality studies would be required to investigate the benefits of EECP and whether they outweigh the common adverse events.

Section Summary: Heart Failure
The evidence for the use of EECP in heart failure includes 2 RCTs that reported on clinical outcomes. One study reported modest improvements for some outcomes and none for others. A second study reported improvements in the 6-minute walk test but had methodologic limitations that, in turn, limited the conclusions that could be drawn from the study. The observational studies added 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 would be needed to determine whether EECP is a useful treatment for heart failure.

OTHER CONDITIONS RELATED TO ISCHEMIA OR VASCULAR DYSFUNCTION

Clinical Context and Therapy Purpose
The purpose of enhanced EECP is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as guideline-directed medical management, in patients with other indications related to ischemia or vascular dysfunction.

The question addressed in this evidence review is: Does the use of EECP improve the net health outcome in individuals with other indications related to ischemia or vascular dysfunction?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with other indications related to ischemia or vascular dysfunction.

Interventions
The therapy being considered is EECP. EECP is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return.

Comparators
Comparators of interest include guideline-directed medical management.

Outcomes
The general outcomes of interest are overall survival, symptoms, morbid events, and functional outcomes.

The limited available literature has followed patients for up to 6 months; in practice, length of follow-up would depend upon the condition being treated.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
The use of EECP for other conditions associated with ischemia or vascular dysfunction has been investigated. Fraser and Adams (2009) evaluated interventions for central retinal artery occlusion in a Cochrane review.[32,]Werner et al (2004), in 1 of the 2 RCTs identified, compared hemodilution with a single 2-hour EECP treatment against hemodilution without further intervention. (2004), the EECP intervention was a single, 2-hour treatment.[33,] According to reviewers, in this study, 20 patients were randomized but not blinded, and no sham treatment was given. Primary outcomes were Doppler flowmetry of retinal perfusion and visual acuity.

Published registry studies have also demonstrated improvements in erectile function. Lawson et al (2007) showed improved erectile function in in a study by Lawson et al (2007) of 120 men prospectively enrolled from 16 centers.[34,] Three of 5 domains of the International Index of Erectile Function were statistically improved with EECP treatment (erectile function, intercourse satisfaction, overall satisfaction), and the total score improved from 28 to 32, a statistically significant improvement. The noncomparative design of this study makes drawing conclusions on treatment efficacy difficult.

Preliminary studies from Asia have also reported on early results using EECP to treat the lower extremities after acute ischemic stroke.[35,]Lin et al (2012), in a Cochrane review, (2012) assessed 2 RCTs of EECP in acute ischemic stroke and concluded that the methodologic quality of the studies was poor, and reliable conclusions could not be reached from this evidence.[36,]

Sardina et al (2016) reported on an RCT that allocated 30 patients with type 2 diabetes in a 2:1 ratio to EECP (n = 20) or standard care for diabetes (n = 10), and reported results out to 3[37,] and 6 months.[38,] At 6-month follow-up, patients in the EECP group had significant decreases in a variety of biomarkers of advanced glycation end products, inflammation, and oxidative stress; the percent change in advanced glycation end products and receptor of advanced glycation end products differed significantly between groups (P<.05).

Summary of Evidence
For individuals who have chronic stable angina who receive EECP, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. There is a single-blind RCT that includes clinical outcomes, and it reported benefit on only 1 of 4 main angina outcomes. Additional small RCTs have reported changes in physiologic measures associated with EECP but did not provide relevant evidence on clinical efficacy. Because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect, more RCT evidence is needed. Observational studies, including registry studies with large numbers of patients, add little to determinations of efficacy.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure who receive EECP, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. One RCT that reported on clinical outcomes found a modest benefit with EECP on some outcomes but not others. A second RCT reported improvements on the 6-minute walk test with EECP but had methodologic limitations; RCT findings ultimately proved inconclusive. The observational studies on EECP in heart failure have limited ability to inform the evidence on EECP due to the multiple confounding variables for cardiac outcomes and the potential for a placebo effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have other conditions related to ischemia or vascular dysfunction who receive EECP, the evidence includes RCTs, registry studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. Two RCTs have assessed use of EECP for treatment of central retinal artery occlusion; both trials had methodologic limitations. Registry studies of erectile function have reported improvements for some outcomes with ECCP but design shortcomings limit conclusions drawn. EECP has also been used to treat acute ischemic stroke, but the evidence base is not robust. EECP has been used in a small RCT to treat type 2 diabetes. Reported follow-up was short-term. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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.

In response to requests, input was received from 3 academic medical centers while this policy was under review in 2008 and 2010. Reviewers agreed with the conclusion that enhanced external counterpulsation was investigational. Some reviewers commented on the potential use of enhanced external counterpulsation in those with angina not amenable to surgical interventions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Joint Guidelines from the American College of Cardiology Foundation, American Heart Association et al

In 2012, the American College of Cardiology Foundation, American Heart Association, and 5 other medical societies published joint guidelines that recommended: "[patients with stable ischemic heart disease who indicate for enhanced external counterpulsation (EECP)] may be considered for relief of refractory angina." This recommendation was class IIb, based on level B evidence (i.e., the efficacy of the intervention is not well established, and further studies would be helpful).[39,]

In 2014, the American College of Cardiology Foundation and American Heart Association updated these joint guidelines. [40,] Based on this review, the groups did not change their recommendation on EECP from the 2012 guidelines.

In 2013, the American College of Cardiology Foundation and American Heart Association issued guidelines on the management of heart failure but did not address EECP.[41,]The 2017 focused update also did not address EECP.[42,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03857022	An Open-label Study to Evaluate the Effects of Enhanced External Counterpulsation on Tapering Inotropic Agents, Reduction of Brain Natriuretic Peptide and Rehospitalization of Patients With Heart Failure	40	Nov 2020 (status=unknown)

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS

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

ICD-10 Diagnoses

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	• 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.
Effective 11-01-2007	• Policy clarified by adding, "Any request for repeat EECP must be reviewed."
	• References were updated.
06-26-2013	Updated the Description section.
	Added Medical Policy and Coding Disclaimers.
	In Policy section: ▪ In the Utilization section, removed #2, "An office visit will be allowed in addition to G0166 and 92971." ▪ Moved statement, "Any request for repeat EECP must be reviewed." to the Utilization section.
	Added the Rationale section.
	Updated and formatted the Reference section.
02-05-2014	In Coding section: ▪ Added ICD-10 Diagnosis *(Effective October 1, 2014)*
03-18-2015	Updated Description section.
	In Policy section: ▪ Added Policy Guidelines, "This policy only addresses the outpatient uses of enhanced external counterpulsation (EECP), ie, for the treatment of chronic stable angina or heart failure. This policy does not address its use for unstable angina pectoris, acute myocardial infarction, or cardiogenic shock."
	Updated Rationale section.
	Updated References section.
10-12-2016	Updated Description section.
	Updated Rationale section.
	Updated References section.
11-08-2017	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed ICD-9 codes.
	Updated References section.
06-22-2018	Updated Description section.
	Updated Rationale section.
	Updated References section.
06-19-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.
03-23-2021	Updated Description section.
	Updated Rationale section.

	Updated References section.
07-02-2021	Updated Rationale section.

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