

Subject: External Counterpulsation (ECP) for cardiac indications (Angina, Heart failure, Cardiogenic shock)		Original Effective Date: 3/11/10
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PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: <http://www.cms.hhs.gov/center/coverage.asp>.

FDA INDICATIONS

Several external counterpulsation (ECP) devices have been approved via the FDA 510(k) process for treatment of one or more of the following indications: stable or unstable angina pectoris; acute myocardial infarction (MI); cardiogenic shock; heart failure. All systems are classified as Class III devices.²

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

ECP is approved for coverage in the treatment of patients with stable and severe angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who are not candidates for surgical intervention. Although ECP devices have been approved by the FDA for use in treating a variety of conditions, including unstable angina pectoris, acute MI, heart failure, and cardiogenic shock, Medicare coverage is limited to ECP use in patients with stable angina pectoris since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Other uses of ECP and similar devices remain noncovered. In addition, the noncoverage of hydraulic versions of these types of devices remains in force. A full course of therapy usually consists of 35 treatments, 1 hour in length, which may be offered once or twice daily, usually 5 days per week.³

INITIAL COVERAGE CRITERIA

External counterpulsation may be authorized when **ALL** of the following criteria are met:

- Cardiologist or Cardiothoracic surgeon ordering the device¹
- Documented cardiac work-up within four months of commencing therapy
- New York Heart Association (NYHA) or the Canadian Cardiovascular class (CCS) or III or IV angina refractory to treatment with or contraindicated to all of the following:^{5,45}
 - ~~○ Ace inhibitors~~
 - Beta-blockers
 - Calcium channel blockers
 - Long-acting nitrates
- Symptoms continue following angioplasty or revascularization procedures **OR** patient is not a candidate for angioplasty or revascularization due to significant comorbidity or coronary anatomy not amendable to invasive correction^{1,3}
- None of the following contraindications:^{1,9,10}
 - Arrhythmias that may interfere with machine triggering (e.g., uncontrolled atrial fibrillation or flutter or very frequent premature ventricular contractions, heart rate > 120)
 - Bleeding predisposition
 - Coagulopathy with an INR of prothrombin time greater than 2.5
 - Severe peripheral artery disease (reduced vascular volume and muscle mass may prevent counterpulsation)
 - Venous disease (phlebitis, varicose veins, stasis ulcers, prior or current deep vein thrombosis or pulmonary embolism)
 - Presence of aortic aneurysm requiring surgical repair ($\geq 5\text{mm}$)¹⁰ or dissection (diastolic pressure augmentation may be deleterious)
 - Severe hypertension (>180/110)
 - Severe congestive heart failure with ejection fraction < 30%
 - Aortic insufficiency (regurgitation would prevent diastolic augmentation)
 - Cardiac catheterization or arterial puncture within 2 weeks (bleeding risk at puncture site)
 - Pregnancy (effects of ECP on the fetus have not been studied)

Initial Authorization Coverage:

- 1-hour treatment sessions, 5 days a week for a total of 35 treatment sessions (7 weeks)¹

CONTINUATION OF THERAPY

Repeat External Counterpulsation treatment has no proven value.^{35,36}

COVERAGE EXCLUSIONS

All other requests for External Counterpulsation or indications that are not included in the ‘Coverage Criteria’ section above are considered **experimental/investigational** or not a covered benefit. This may not be all-inclusive and is subject to change based on research and medical literature.

Repeat External Counterpulsation treatment is considered *experimental/ investigational and not a covered benefit*.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The ECP device used in most, if not all, studies for treatment use is offered by the manufacturer Vasomedical, Inc.⁹ Enhanced external counterpulsation (ECP) involves sequential pneumatic compression of the legs coordinated with cardiac contractions.^{1,9} ECP is designed to increase diastolic aortic blood pressure, improve venous blood return, and decrease afterload on the left ventricle. The counterpulsating action of EECP therapy increases venous return and cardiac output. During EECP therapy systolic unloading is improved by increasing blood flow and oxygen to the heart, while diastolic augmentation increases the energy supply to the heart thus reducing the workload of the heart. The hemodynamic effects of EECP also increase the pressure gradient as well as the release of vascular growth factors that enhance coronary collateral circulation. The increase of blood flow increases shear stress on the walls of the arteries and improves endothelial function. The goal of ECP is to increase perfusion during diastole in patients with chronic angina pectoris, relieving pain and reducing impairment. ECP has also been investigated in patients with congestive heart failure, myocardial infarction, and cardiogenic shock.

Heart Failure - Stages & Classifications

The New York Heart Association (NYHA) classification system⁴⁶ is used to classify symptoms of heart disease, including heart failure. Symptoms are graded based on how much they limit your *functional capacity* (your ability to perform basic physical tasks).

<u>NYHA Heart Failure Classification</u>	
<u>Class</u>	<u>Description</u>
<u>1 (Mild)</u>	<u>No limitation of physical activity - ordinary physical activity doesn't cause tiredness, heart palpitations, or shortness of breath</u>
<u>2 (Mild)</u>	<u>Slight limitation of physical activity – comfortable at rest, but ordinary physical activity</u>

<u>NYHA Heart Failure Classification</u>	
	<u>results in tiredness, heart palpitations, or shortness of breath</u>
<u>3 (Moderate)</u>	<u>Marked or noticeable limitations of physical activity – comfortable at rest, but less than ordinary physical activity causes tiredness, heart palpitations, or shortness of breath</u>
<u>4 (Severe)</u>	<u>Severe limitation of physical activity – unable to carry out any physical activity without discomfort. Symptoms also present at rest. If any physical activity is undertaken, discomfort increases.</u>

The following table shows the Canadian Cardiovascular Society (CSS) Functional Classification of Angina:¹²

CCS Functional Classification of Angina

Class	Activity Evoking Angina	Limits to Physical Activity due to angina
I	Ordinary activity, prolonged exertion	None
II	Walking > 2 blocks or > 1 flight of stairs	Slight
III	Walking < 2 blocks or < 1 flight of stairs	Marked
IV	Minimal or at rest	Severe

GENERAL INFORMATION

Summary of Medical Evidence

ECP therapy provides a treatment alternative for severe chronic stable angina patients with or without heart failure who are unsuitable candidates for revascularization, angioplasty or who have unrelieved angina despite previous surgical intervention. Numerous clinical trials have demonstrated positive responses among approximately 80% of the patients undergoing ECP therapy, including reductions in angina, increased exercise tolerance, and in some studies decreased nitrate use.¹ One randomized- control trial and several prospective studies have presented data to support these findings. Several mechanisms have been reported to be responsible for the clinical benefits of this therapy including improvement in endothelial function,⁴² improvement in blood pressure,⁴¹ reduction in inflammation,³³ promotion of collateral blood flow³¹ and the production of peripheral training effects similar to exercise therapy.³² However, there are study limitations noted in all reported studies. Comparison studies have indicated a greater treatment effect with percutaneous coronary interventions compared with ECP therapy. ECP is recommended to be limited to those with debilitating angina who cannot

be revascularized and who are taking maximal antianginal medications due to the lack of high quality randomized-control trials.

There is insufficient data to support the use of ECP therapy for any other cardiac indication such as congestive heart failure as a primary diagnosis, unstable angina, cardiogenic shock, or myocardial infarction.

Results of studies of external counterpulsation for stable angina

The objective of the multi-center MUST-EECP prospective randomized, double-blinded, placebo-controlled study-control trial was to assess the safety and efficacy of ECP in patients (between 21 and 81 years of age) with chronic stable angina.^{5,11} Participants (n=139) were randomized to ECP (n=72) of 35 1-hour sessions at a pressure of 300 mmHg, or sham ECP (n=67). Sham ECP was similar to ECP, with the exception that suboptimal pressure of 75 mmHg was used. This was described as insufficient to alter patient blood pressure, but sufficient to preserve the appearance and feel of ECP treatment. Patients with a Canadian Cardiovascular Society (CCS) grading classification between I and III, documented evidence of coronary artery disease and a positive exercise treadmill test for ischemia were eligible for inclusion. There was no requirement that patients should be refractory to standard antianginal medication. Patients with class IV angina, overt congestive heart failure (ejection fraction \leq 30%), unstable angina, myocardial infarction or coronary artery bypass grafting in the previous 3 months, cardiac catheterization in previous 2 week period, significant valvular disease, blood pressure > 180/100mmHg, non-bypassed left main stenosis > 50% were excluded. Results indicated that ECP significantly improved time to ischemia during exercise testing and some reduction in angina episodes compared with sham treatment. There was reported placebo effect of sham treatment. The study limitations included small sample size; angina episodes were reported retrospectively, blinding effect unknown, clinical significance of small gain (mean gain 37 seconds) is unknown.

Two larger (n=306; n=175) multicenter uncontrolled prospective studies^{13,14} and two smaller study (n=47)^{15,32} with similar inclusion and exclusion criteria as the original RCT were conducted on chronic stable angina¹⁴ patients CCS classification I-IV, chronic refractory angina^{13,15} not candidates for further revascularization.^{15,32} All patients received 35 hours of ECP treatment in 1 hour session 5 days per week for 7 weeks in both studies. CCS angina class improved in 88% of 395 patients in the first study.¹³ A poor correlation between hemodynamic parameters and clinical improvement was reported. A similar study performed using registry data demonstrated a correlation between greater diastolic augmentation and treatment benefit.²⁸ The second study results reported a \geq 1 CCS angina class improvement in 88% of patients.¹⁴ A significant improvement in mean exercise duration in patients who had maximal post-ECP RN stress tests. Anginal symptoms, dyspnea on exertion and quality of life were reported with a significantly improved 6-minute walking distance to 1025 +/- 234 feet versus 653 +/- 249 feet following 35 treatment days.³² ECP did not significantly impact left ventricular end-diastolic and end-systolic dimensions or left ventricular ejection fraction.

Several prospective uncontrolled case series had limited follow-up and lack of consistent key outcome measures reported.¹⁵⁻²² These studies consistently reported that ECP therapy was associated with improved outcomes for patients with angina. The therapy was reported to be safe and effective. The study protocols remained consistent with previous study protocols.

One investigator group conducted four uncontrolled studies using radionuclide exercise stress scans to evaluate results.^{16,18,23,24} Substantial improvement in myocardial perfusion was reported following 35 hours of ECP therapy. One study resulted in long-term follow-up of five years.¹⁸ Results demonstrated 79% of patients responded to therapy with persistent improvements for years. ECP nonresponders experienced significantly more major cardiovascular events (86%, $P < 0.01$) than responders (23%).

Patient registry data studies were conducted that support the conclusion that ECP therapy may result in the reduction of angina symptoms and decrease use of nitroglycerin needs.^{25-27,29,30,44} A large follow-up study of 1,427 patients from 36 registered centers were prospectively followed.³⁴ One thousand sixty one patients completed follow-up as 220 patients died. The majority of patients had a prior surgical or percutaneous intervention and (82%) were unsuitable for further coronary intervention. The percentage of patients with severe angina (CCS classification III or IV) were reduced from 89% to 25%, $p < 0.001$. The CCS class was improved by minimally one class in 78% of the patients and by 2 classes or more in 38% of patients. The results were sustained in 74% of patients during three year follow-up. Several studies did not find a correlation between the hemodynamic effects of ECP and the degree of symptom relief. The lack of a control group in these studies, make it difficult to determine the magnitude of the ECP treatment as placebo effect was noted in the response. A subgroup analysis of registry data demonstrated similar outcomes for revascularization candidates and for unsuitable candidates.²⁶ One study compared data from the International Enhanced External Counterpulsation Patient Registry (IEPR) cohort with data from the National Heart, Lung, and Blood Institute (NHLBI) registry of coronary interventions for patients who had undergone a percutaneous coronary intervention (PCI).²⁷ The analysis demonstrated that PCI was more effective in eliminating angina pain compared with ECP, survival rates were consistent between the two groups.

Shah and colleagues (2010) performed a meta-analysis to evaluate the true magnitude of benefit from enhanced external counterpulsation (EECP) by determining the effect of EECP on Canadian Cardiovascular Society (CCS) angina class in patients with chronic stable angina. 13 prospective studies were included that evaluated patients with stable angina and reported adequate data on CCS angina class. A systematic literature search of studies published between 1950 and February 2009 was performed. Studies were included for meta-analysis if they were reported in the English language, included human subjects, had a prospective study design, and reported adequate data on CCS angina class. The EECP treatment consisted of 35 sessions-1 hour/day, 5 days/week, for 7 weeks. Improvement in angina class was reported as the weighted proportion of patients improving by at least one CCS class from before to after EECP treatment. Heterogeneity was assessed by performing subgroup analyses and using the Cochran Q statistic. Publication bias was assessed by inspection of

funnel plots and the Egger bias statistic. Among the 13 studies incorporating 949 patients, angina class was reduced by at least one CCS score in 86% of the patients (95% confidence interval 82-90%, Q statistic $p=0.008$). Inspection of funnel plots showed some asymmetry, but the Egger bias statistic showed no publication bias ($p=0.97$). The results of the meta-analysis indicated that further long-term studies are needed to determine the place of EECP therapy in the management of chronic stable angina. Currently, EECP therapy should be considered for patients with stable angina who are refractory to or not suitable for invasive therapy and/or medical management.⁴⁹

Casey and colleagues (2011) published the results of a randomised controlled trial evaluating external counterpulsation in patients with chronic angina. Patients with coronary artery disease and chronic angina pectoris were randomized (2:1 ratio) to 35 1-hour sessions of EECP ($n = 28$) or sham EECP ($n = 14$). Central and peripheral arterial pulse-wave velocity and aortic wave reflection (augmentation index) were measured using applanation tonometry before, and after 17 and 35 1-hour treatment sessions. Wasted left ventricular pressure energy and aortic systolic tension-time index, markers of left-ventricular myocardial oxygen demand, were derived from the synthesized aortic pressure wave. Exercise duration, anginal threshold, and peak oxygen consumption were measured using a graded treadmill test. Central arterial stiffness and augmentation index were decreased after 17 and 35 sessions in the treatment group. Measurements of peripheral arterial stiffness were decreased after 35 sessions in the treatment group. Changes in aortic pressure wave reflection resulted in decreased measurements of myocardial oxygen demand and wasted left ventricular energy. No changes in central or peripheral arterial stiffness were observed in the sham group. Furthermore, measurements of exercise capacity were improved in the EECP group but unchanged in the sham group. The authors concluded that EECP therapy decreases central and peripheral arterial stiffness and may explain improvements in myocardial oxygen demand in patients with chronic angina pectoris after treatment.⁵⁰

McKenna and colleagues (2009) performed a systematic review to determine the clinical effectiveness and cost-effectiveness of enhanced external counterpulsation (EECP) compared with usual care and placebo for refractory stable angina and heart failure, and to undertake analyses of the expected value of information to assess the potential value of future research on EECP. Five studies were included in the review. In the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP), time to greater than or equal to 1-mm ST segment depression (exercise-induced ischaemia) was statistically significantly improved in the EECP group compared with the control group (sham EECP), mean difference (MD) 41 seconds [95% confidence interval (CI) 9.10-73.90]. However, there was no statistically significant difference between the EECP and control groups in the change in exercise duration from baseline to end of treatment, self-reported angina episodes or daily nitroglycerin use, and the clinical significance of the limited benefits was unclear. There was also a lack of data on long-term outcomes. There were more withdrawals due to adverse events in the EECP group than in the control group, as well as a greater proportion of patients with adverse events [relative risk (RR) 2.13, 95% CI 1.35-3.38]. The three non-randomised studies compared EECP with elective percutaneous coronary intervention (PCI) and usual care. There was a high risk of selection bias in all three studies and the results should be treated with considerable caution. The study comparing an EECP registry with a PCI registry reported similar 1-year all-cause mortality in both groups. In the Prospective Evaluation of EECP in Congestive

Heart Failure (PEECH) trial, patients with heart failure were randomised to EECP or to usual care (pharmacotherapy only). At 6 months post treatment, the proportion of patients achieving at least a 60-second increase in exercise duration was higher in the EECP group (RR 1.39, 95% CI 0.89-2.16), but the proportion with an improvement in peak VO₂ was similar in both groups. The clinical significance of this is unclear. The proportion of patients in the EECP group with an improvement in New York Heart Association classification was higher (RR 2.25, 95% CI 1.25-4.06) at 6 months, as was mean exercise duration, MD 34.6 (95% CI -4.86 to 74.06). There were more withdrawals in the EECP group than in the control group as a result of adverse events (RR 1.05, 95% CI 0.67-1.66). There were limitations in the general ability of results of the trial and, again, a lack of data on long-term outcomes. The review of cost-effectiveness evidence found only one unpublished study but demonstrated that the long-term maintenance of quality of life benefits of EECP is central to the estimate of its cost-effectiveness. The incremental cost-effectiveness ratio of EECP was 18,643 pounds for each additional quality-adjusted life-year (QALY), with a probability of being cost-effective of 0.44 and 0.70 at cost-effectiveness thresholds of 20,000 pounds and 30,000 pounds per QALY gained respectively. Results were sensitive to the duration of health-related quality of life (HRQoL) benefits from treatment. The authors concluded that the results from a single randomised controlled trial (MUST-EECP) do not provide firm evidence of the clinical effectiveness of EECP in refractory stable angina or in heart failure. High-quality studies are required to investigate the benefits of EECP, whether these outweigh the common adverse effects and its long-term cost-effectiveness in terms of quality of life benefits.⁵²

Studies regarding repeat ECP for stable angina pectoris patients

There is insufficient evidence to support repeat ECP therapy. There are no prospective or randomized-control studies to support the safety or effectiveness for conducting repeat therapy. IECP registry data reports an initial decrease in angina and a concomitant decrease in nitroglycerin use after the second course of therapy. However, at 2 years repeat ECP patients had worse angina compared with those who did not undergo repeat ECP therapy. Repeat ECP patients did not sustain symptomatic improvement and patients required high a high percentage of continued nitroglycerin use in the second study.

A study evaluating IECP registry data evaluated 1,192 patients from 29 different centers who underwent a full complete 35 hour first course of ECP for chronic angina pectoris.³⁵ Approximately, 86% had previous revascularization treatment, 90% had CCS classification of III or IV at baseline, with mean angina episodes of 11 per week. Nitroglycerin was used by 81% of the patients, calcium channel blockers by 48%, Beta blockers by 76% and hypolipidemic agents by 76%. A decrease of ≥ 1 CCS class was demonstrated in 86% of patients after the initial course of ECP and nitroglycerin use was discontinued by 57% of patients. A repeat course of ECP was performed on 194 patients within 2 years of the initial course. Data was available for 78% or 152 of the patients receiving repeat ECP treatment. Repeat ECP was initiated due to increased angina in 62% of patients and persistent angina in 38% of the patients. The rate of repeat ECP for patients who reported an initial angina decrease was 19% compared with 12% for those who had no initial decrease (p= 0.07). A significant

decrease in angina for those who underwent repeat ECP was demonstrated (70%) this rate was significantly less than the 89% who initially achieved angina relief. Anginal symptoms remained significantly worse in patients who had repeat ECP at a 2-year follow-up. Repeat ECP patients had class 0 to 2 angina (59%) compared with 82% of those who did not undergo repeat ECP ($p < 0.001$). The need for nitroglycerin use was more common in patients that underwent repeat ECP (63%) versus those who did not undergo a repeat ECP (45%, $p < 0.001$).

A second study was found evaluating the causes and results of retreated patients who failed to complete an initial 35-hour course of ECP.³⁶ IECF registry data of 2,311 successive angina patients was evaluated, 13.5% of these patients failed to complete their initial course of ECP and 28.3% of these had repeat ECP within one year. The group that did not complete ECP therapy had 21.7% of the patients decrease at least one CCS classification after initial ECP therapy versus 83.4% in the group that completed all 35 treatments ($p < 0.001$). The incomplete group achieved at least one CCS class reduction of 66.2% after repeat treatment versus 69.4% of in the initial group that completed all 35 treatments ($p=NS$). Anginal episodes significant decreased after repeat treatment in both the incomplete group (from 8.3 ± 8.9 to 4.3 ± 7.3 , $p < 0.05$) and the complete group (from 8.8 ± 11.0 to $3.7 \pm 3.7 \pm 7.1$, $p < 0.001$). The percentage of patients using nitroglycerin in the incomplete group remained relatively high at 56.8% compared with 34.6% in those who completed an initial treatment course of 35 hours. Using a logistic regression model, the predictors of failure to complete the initial course of ECP were: Heart failure, use of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, female gender and use of nitroglycerin. The majority of patients stopped treatment due to clinical events, 54.7% (e.g., unstable angina, myocardial infarction, emergency PCI/CABG, new CHF or exacerbation), personal reasons, and 7.1 % for unknown reasons.

Results of studies of external counterpulsation for heart failure/other cardiac conditions

There is insufficient data to support the safety and efficacy of performing ECP therapy for cardiac conditions such as heart failure, myocardial infarction, or cardiogenic shock. There are no high quality studies published in support of the safety or efficacy of ECP for other cardiac related diagnoses.

A multicenter randomized-control Prospective Evaluation of EECF in Congestive Heart Failure (PEECH) trial with 187 patients evaluated the efficacy of ECP in the treatment of mild to moderate heart failure. Patients were randomized to ECP of 35 1-hour sessions over 7-8 weeks as an adjunct to pharmacotherapy or usual care (pharmacotherapy only). It was not possible to blind patients or those delivering the intervention as the comparator was usual care. Medical therapy was optimized for all patients in using the recommended guidelines of the Heart Failure Society of America prior to randomization. Only patients with stable heart failure (secondary to ischemic heart disease or idiopathic-dilated cardiomyopathy), with LVEF less than 35% and NYHA class I or II were eligible for inclusion. The study excluded patients with acute coronary syndrome experienced within 6 weeks of the enrollment, luminal stenosis $\geq 50\%$ without surgical bypass, CABG in previous 3 months, PCI in previous 6 weeks, cardiac catheterization within previous 2 weeks, arrhythmias that could interfere with treatment, COPD patients with forced expiratory volume of 1 second ≤ 1.51 , acute

myocarditis, significant valvular heart disease, uncontrolled hypertension, and history of deep vein thrombosis, pulmonary embolism, phlebitis, or stasis ulcer. The majority of patients (76%) were being treated with ACE inhibitors. Assessments were at baseline, end of treatment and 6-month follow-up. The primary outcomes were the proportion of participants with at least a 60-second increase in exercise duration and the proportion with at least 1.25-ml/kg/minute increase in peak VO₂. The proportion of patients not completing the study was higher for the ECP group (23.7%) than for the control group (13.8%) mainly due to a higher frequency of adverse events (the most prevalent was worsening of heart failure). A significantly greater proportion of ECP than control group patients had at least a 60-second increase in exercise duration from baseline to 6 months (35% versus 25%, $p = 0.016$), but the proportion with an improvement in peak VO₂ was similar (23% versus 24%, $p = 0.698$). These results at 6 months were similar at the 3 month follow-up. The results from the secondary outcomes were also mixed. There was a statistically significant proportion of patients in the ECP group with an improvement in NYHA classification post treatment, 3 months' and 6 months' follow-up (RR 2.25, 95% CI 1.25-4.06). However, although there was a statistically significant improvement in quality of life with ECP compared with control post treatment and at the 3-month follow-up, no greater benefit with ECP was demonstrated 6 months. The clinical benefit to heart failure patients of a 35-second increase in mean exercise duration and a difference of 10% achieving a minimum 60-second increase in exercise duration is unclear. The limited follow-up means that the effects of EECPP on the long-term outcomes of these patients cannot be determined.

A prospective subgroup analysis of the PEECH trial was conducted focusing on participants greater than 64 years of age. The study results indicated that at 6 months, exercise responder rate and peak VO₂ were significantly improved compared to the control group. NYHA classification was significantly improved compared to controls at 3 months follow up but not at 6 months and Minnesota Living with Heart Failure scores did not demonstrate a significant difference. The authors warn that the subgroup analysis should be interpreted with caution and may not be representative of a larger heart failure population.

A retrospective study reviewing IEPR registry data evaluated 548 patients diagnosed with congestive heart failure out of a total of 1,957 patients evaluated.⁴⁰ The majority of patients had prior revascularization, percutaneous artery intervention or CABG procedure intervention. The CHF cohort received a mean of 33.1 hours of treatment with 78% completing the treatment course as prescribed. A higher drop-out rate was noted in the CHF group. Major adverse cardiac events (MACE) had an overall rate of 2.4% was higher but comparable to the rate of 1.7% in patients without CHF. There was a significantly higher rate of heart failure (5.5%) in CHF patients than inpatients without CHF (0.2%) ($p < 0.001$). The combined endpoints of death, MI, unstable angina, CABG and PCI was not significantly increased in the CHF group (5.3% versus 3.4, $p=NS$). Significant improvement in CCS angina class was seen in both groups. Patients in the CHF cohort were significantly less likely to have a reduction in their angina with ECP treatment. The CHF cohort reported 75% of patients had the same or less angina at the 6 month follow-up compared with immediately following treatment. MACE had occurred in 14.4% of patients: death in 7.9%, MI in 3.6%, CABG in 1.1% and percutaneous transluminal coronary angioplasty in 2.5%. CHF exacerbations were noted in 7.2% of patients

and 19.1% were hospitalized for various cardiac reasons. The authors concluded the mean improvement was less in the CHF cohort immediately following ECP and fewer patients were able to complete treatment. Treatment discontinuation was mainly related to CHF exacerbation. The CHF cohort maintained angina reduction in the 6-month follow-up but were more likely to experience a major adverse cardiac event or CHF exacerbation.

A review of literature was conducted regarding the clinical use of ECP in angina and heart failure patients as a therapeutic option for treatment in patients who remain intolerant to treatment or remain symptomatic.³⁸ The authors suggest that ECP has proven to provide symptomatic relief in angina pectoris patients but efficacy for heart failure patients is still uncertain.

Buschmann and colleagues (2010) performed a prospective, controlled, proof-of-concept (The Art.Net.-2 Trial) study to determine if a treatment course with external counterpulsation (over 7 weeks) can induce the growth of myocardial collateral arteries. External counterpulsation is a non-invasive technique suggested to promote the growth of myocardial collateral arteries via increase of shear stress. Inclusion criteria are (1) age 40 to 80 years, (2) stable coronary disease, (3) a residual significant stenosis of at least one epicardial artery and (4) a positive ischemic stress-test for the region of interest. A total of 23 patients (age 61 +/- 2.5 years) with stable coronary artery disease and at least one haemodynamic significant stenosis eligible for percutaneous coronary intervention were prospectively recruited into the two study groups in a 2 : 1 manner (ECP : control). One group (ECP group, n = 16) underwent 35 1-h sessions of ECP in 7 weeks. In the control group (n = 7), the natural course of collateral circulation over 7 weeks was evaluated. All patients underwent a cardiac catheterization at baseline and after 7 weeks, with invasive measurements of the pressure-derived collateral flow index (CFIp, primary endpoint) and fractional flow reserve (FFR). In the ECP group, the CFIp (from 0.08 +/- 0.01 to 0.15 +/- 0.02; P < 0.001) and FFR (from 0.68 +/- 0.03 to 0.79 +/- 0.03; P = 0.001) improved significantly, while in the control group no change was observed. Only the ECP group showed a reduction of the Canadian Cardiovascular Society (CCS, P = 0.008) and New York Heart Association (NYHA, P < 0.001) classification. The authors concluded that there is direct functional evidence for the stimulation of coronary arteriogenesis via ECP in patients with stable coronary artery disease. These data might open a novel noninvasive and preventive treatment avenue for patients with non-acute vascular stenotic disease.⁴⁷

Hayes, Cochrane, UpToDate, MD Consult etc.

A Hayes Directory report is available for external counterpulsation evaluating the technology for patients with cardiac conditions.¹ An updated review was completed July, 2009 with no changes in content based upon new studies reviewed. There is moderate evidence to support external counterpulsation in certain patients with chronic stable angina. All other indications have insufficient evidence to support safety and efficacy or are unproven. An updated review was completed in June 2012 with no changes in content based upon the new studies reviewed.

A Cochrane review (2012) is available for external counterpulsation evaluating this procedure for acute ischaemic stroke. Randomised controlled trials (RCTs) in which ECP (started within seven days of stroke onset) was compared with sham treatment or no treatment, or ECP plus routine treatment was compared with routine treatment alone, in patients with acute ischaemic stroke. Two trials involving 160 patients were included. Numbers of death or dependent patients at the end of at least three months follow-up were not reported in either of the included trials. The outcome measure used in the included trials was only the number of participants with improvement of neurological impairment after treatment according to the Modified Edinburgh-Scandinavian Stroke Scale (MESSS) or self-making criteria. ECP was associated with a significant increase in the number of participants whose neurological impairment improved (risk ratio (RR) 1.75, 95% confidence interval (CI) 1.37 to 2.23). Only one trial reported no adverse events. The authors concluded that the methodological quality of the included studies was poor, and reliable conclusions could not be drawn from the present data. High-quality and large-scale RCTs are needed. ⁴⁸

Another Cochrane review (2010) is available for enhanced external counterpulsation evaluating this procedure for chronic angina pectoris. Randomized controlled trials and cluster-randomized trials comparing enhanced external counterpulsation therapy to sham treatment in adults, aged over 18 years, with chronic stable and stable refractory angina pectoris graded Canadian Cardiovascular Society Class III to IV at baseline were reviewed. One trial (139 participants) was included in this review. Poor methodological quality, in terms of trial design and conduct, incompleteness in reporting of the review's primary outcome, limited follow up for the secondary outcomes and subsequent flawed statistical analysis, compromised the reliability of the reported data. The authors concluded that the one relevant trial failed to address the characteristics of interest satisfactorily, in terms of severity of angina, for the participants in this review. Participants with the most severe symptoms of angina were excluded; therefore the results of this study represent only a subsection of the broader population with the disorder, are not generalizable and provide inconclusive evidence for the effectiveness of enhanced external counterpulsation therapy for chronic angina pectoris. ⁵¹

Professional Organizations

- The ACC, in combination with the American Heart Association (AHA), American Society of Internal Medicine (ASIM), and the American College of Physicians (ACP), published treatment guidelines for chronic stable angina in 1999.⁴ The report indicates that, although there have been several small observational studies suggesting benefit from treatment with enhanced ECP (EECP), the available evidence does not support recommending its use in patients with chronic stable angina. These guidelines were updated in 2002⁵ and these recommendations were unchanged. **ECP was not mentioned in the 2007 focused update of the ACC/AHA 2002 guidelines for the management of patients with chronic stable angina. There has been no update to this guideline 2007.** ⁵⁴
- In 2005, the ACC/AHA published guidelines for the treatment of heart failure.⁶ The guidelines state that ECP is still under investigation and cannot be recommended at this time for the management of patients

with symptomatic left ventricular systolic dysfunction. These guidelines were updated in 2009 with unchanged recommendations regarding ECP.⁷ **There has been no update to this guideline since 2009.**

- In 2007, the ACC/AHA updated published treatment guidelines for unstable angina and non-ST-segment elevation MI. These guidelines state that ECP is under investigation as a treatment modality.⁸ **In 2012, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines (Writing Committee published a focused update to the 2011 Guidelines for the Management of Patients with Unstable Angina/Non–ST-Elevation Myocardial Infarction. These guidelines do not mention ECP.**⁵³
- In 2007, the ACC/AHA published updated guidelines for chronic stable angina patients.⁴⁵ No changes to ECP recommendations were made. **There has been no update to this guideline since 2007.**
- **In 2012, the ACCF/AHA/ACP/AATS/PCNA/SCAI/STS published guidelines for stable ischemic heart disease (SIHD). These guidelines mention that enhanced external counterpulsation may be considered for relief of refractory angina in patients with SIHD.**⁵⁵

CODING INFORMATION	
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CPT	Description
92971	Cardioassist-method of circulatory assist; external

HCPCS	Description
G0166	External counterpulsation, per treatment session

ICD-9	Description
413.0-413.9	Angina pectoris
414.0	Coronary artery disease
414.9	Unspecified chronic ischemic heart disease

ICD-10	Description
I20.8	Other forms of angina pectoris
I20.9	Angina pectoris unspecified
I25.111	ASHD native cor art w/angina pectoris doc spasm
I25.118	ASHD native cor art w/other forms angina pectoris

I25.119	ASHD native cor art with uns angina pectoris
I25.701	Atherosclerosis cor art BP gft uns w/ap doc spasm
I25.708	Atherosclerosis cor art BP gft uns angina pectoris
I25.709	Atherosclerosis cor art BP gft uns w/uns angina pectoris
I25.711	Atherosclerosis autol vein cor art BP gft w/ angina pectoris doc spasm
I25.718	Atherosclerosis autol vein CABG w/ other forms angina pectoris
I25.719	Atherosclerosis autol vein cor art bp graft uns angina pectoris
I25.721	Atherosclerosis autol art cabg w/ ap doc spasm
I25.728	Atherosclerosis autol art cabg w/ other form ap
I25.729	Atherosclerosis autol art cabg w/ uns angina pectoris
I25.731	Atherosclerosis nonautol biol cabg w/ap w/doc spasm
I25.738	Atherosclerosis nonautol biol cabg w/other forms ap
I25.739	Atherosclerosis nonautol biol cabg w/uns ap
I25.751	Atherosclerosis native cor art transplant heart w/ ap doc spasm
I25.758	Atherosclerosis native cor art transplant heart w/other forms ap
I25.759	Atherosclerosis native cor art transplant heart w/uns ap
I25.761	Atherosclerosis BP gft cor art tplnt hrt w/ap spasm
I25.768	Atherosclerosis BP gft cor art tplnt hrt with other form ap
I25.769	Atherosclerosis BP gft cor art tplnt hrt with uns ap
I25.791	Atherosclerosis oth cor art bp gft w/ap doc spasm
I25.798	Atherosclerosis oth cor art bp gft other forms ap
I25.799	Atherosclerosis oth cor art bp gft w/unst ap
I25.9	Chronic ischemic heart dz unspecified

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