Name of Policy:
Enhanced External Counterpulsation (EECP)

Policy #: 059       Latest Review Date: January 2014
Category: Medical       Policy Grade: A

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Enhanced external counterpulsation (EECP) is a noninvasive treatment that uses timed, sequential inflation of pressure cuffs on the calves, lower and upper thighs. The pressure produces aortic counterpulsation (i.e., retrograde aortic blood flow) that increases diastolic blood volume and pressure (diastolic augmentation) in the aorta. The cuffs are released at the onset of systole. The decrease in afterload results in increased cardiac output with a lowered systolic pressure. Finger plethysmography is used to synchronize cuff inflation with the cardiac cycle to augment diastolic pressure; decrease left ventricular afterload, and increase venous return. EECP is used to treat angina and congestive heart failure.

A course of treatment typically includes 35 hours performed in one- to two-hour sessions in the physician’s office. The multiple components of EECP include the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms (ECGs) to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

Policy:
Effective for dates of service on or after March 1, 2010:
Enhanced external counterpulsation (EECP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all the following criteria are clearly documented in the patient’s medical record:

- The patient has a diagnosis of stable or unstable angina; and
- The patient has New York Heart Association (NYHA) or Canadian Cardiovascular Society Classification (CCSC) Class III or Class IV angina (see below) and
- The patient is refractive to maximum medical therapy; and
- The patient is not a candidate for a re-vascularization procedure such as percutaneous transluminal coronary angioplasty (PTCA), coronary artery stenting, or coronary artery bypass graft (CABG), because in the opinion of a cardiologist or cardiovascular surgeon* one or more of the following conditions exists:
  - The condition is inoperable;
  - There is a high risk of operative complications or postoperative failure;
  - The coronary anatomy is not readily amenable to such procedure; or
  - There are comorbid conditions which create unacceptable surgical risk; or
- The patient has a diagnosis of stable or unstable angina; and
- The patient has New York Heart Association (NYHA) or Canadian Cardiovascular Society Classification (CCSC) Class III or Class IV angina (see below) and
- The patient is refractive to maximum medical therapy; and
- The only other treatment options available to the patient are transmyocardial laser revascularization (TMLR), cardiac transplant, or participation in a clinical trial.

*A cardiologist or cardiovascular surgeon must evaluate the patient and recommend EECP.
Only one course of treatment of EECP will be covered if the above criteria are met. A repeat course of treatment of EECP will not be covered.

**Enhanced external counterpulsation (EECP) does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for all other conditions; including, but not limited to:

- congestive heart failure in the absence of angina,
- decompensated congestive heart failure with or without angina,
- uncontrolled arrhythmias,
- aortic insufficiency,
- acute myocardial infarction,
- cardiogenic shock,
- severe peripheral arterial disease or phlebitis,
- severe hypertension (BP >180/100mmHg),
- sustained tachycardia (heart rate > 120 beats per minute),
- bleeding diathesis (INR>2.0),
- pregnancy or the potential for pregnancy, and
- in lieu of a physician recommended revascularization procedure such as PTCA, coronary artery stenting, or CAGB
- erectile dysfunction;
- Ischemic stroke.

**Angina Classification**

<table>
<thead>
<tr>
<th>Classification</th>
<th>NYHA</th>
<th>CCSC</th>
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</thead>
<tbody>
<tr>
<td>O</td>
<td>Not applicable</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>I</td>
<td>Patients with no limitation of activities; they suffer no symptoms from ordinary activities</td>
<td>Angina with strenuous exercise</td>
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<tr>
<td>II</td>
<td>Patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion</td>
<td>Angina with moderate exertion</td>
</tr>
</tbody>
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| III            | Patients with marked limitation of activity; they are comfortable only at rest | Angina with mild exertion  
  o Walking 1-2 level blocks at normal pace  
  o Climbing 1 flight of stairs at normal pace |
| IV             | Patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest | Angina at any level of physical exertion |
Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
Approximately 1.3 million patients are admitted to hospitals in the United States with unstable angina each year. Most of these patients can be treated medically or with interventions such as percutaneous angioplasty or coronary artery bypass grafting. However, some of these patients do not respond to medication or are not candidates for invasive revascularization interventions.

Angina is an episodic clinical condition caused by transient myocardial ischemia. Episodes of angina typically follow a crescendo-decrescendo pattern, last one to five minutes, may be caused by periods of exertion or emotional stress and are relieved by rest. The threshold at which angina develops varies among patients and according to the time of day in any single patient. Symptoms of angina are not always consistent, however, and myocardial ischemia may occur in the absence of symptoms in some patients.

The National Heart, Lung and Blood Institute estimate that more than two million Americans have heart failure and approximately 400,000 new cases are diagnosed per year. The effectiveness of EECP has been studied for angina, congestive heart failure, acute myocardial infarction, and cardiogenic shock.

EECP is thought to increase coronary artery perfusion by augmenting diastolic pressure which displaces a volume of blood backwards 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 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.

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. EECP, on the other hand, is thought to provide a permanent effect on the heart by enhancing the development of coronary collateral development.

The reported benefits of EECP include reduction of angina and nitrate use, increased exercise tolerance, favorable psychosocial effects and enhanced quality of life, as well as prolongation of the time to exercise-induced ST-segment depression and an accompanying resolution of myocardial perfusion defects.

A 1999 TEC assessment offered the following observations and conclusions regarding EECP:
• “The most important evidence about EECP consists of data from the Multicenter Study of Enhance External Counterpulsation (MUST-EECP). This study was a randomized, controlled, double-blinded protocol comparing active treatment to placebo among 139 patients with chronic stable angina.

• In this trial there was a statistically significant increase in time to ST segment depression in the treated patients’ vs the sham treated patients, suggesting a real physiologic post-treatment effect of EECP. However, the clinical significance of this mean 37-second increase is unclear. The trial also reported a significant reduction in the number of anginal episodes, but statistical significance was only reached when the analysis was limited to those patients who had completed 34 out of 35 sessions. Thus it is unclear whether these results are related in part to selection bias or a true treatment effect.

• The assessment concluded that there is not sufficient evidence to draw conclusions about the long-term benefits of EECP, its effect on morbidity or mortality, and its place in the continuum of management options for patients with chronic stable angina, particularly if it is suggested as an alternative to surgical revascularization.”

MUST-EECP continues to be the most compelling study in the literature regarding EECP. However, recent evidence suggest that EECP may improve symptoms via various mechanisms, including improvement in endothelial function, promotion of collateral circulation, enhancement of ventricular function, and peripheral effects similar to those observed in response to regular physical exercise. Results from the International EECP Patient Registry (IEPR) and the EECP Clinical Consortium have demonstrated that the symptomatic benefit observed in controlled studies also translates to the patient population seen in clinical practice. Also, follow-up data indicates that the clinical benefit may be maintained for up to five years in patients with a favorable initial clinical response.

Although FDA approved for use in the treatment of congestive heart failure, there is not sufficient evidence in the peer-reviewed literature concerning outcomes and long term effects.

**August 2007 Update**
No new peer-reviewed published literature was found that would alter the coverage statement of this policy.

**August 2009 Update**
CMS has covered the use of external counterpulsation (ECP) since July 1, 1999 for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass. All other cardiac conditions not otherwise specified as nationally covered for the use of ECP remain nationally non-covered.

In 2007, the ACC/ AHA Task Force on Practice Guidelines updated the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction (UA/NSTEMI) does not have a recommendation for external counterpulsation.
Braunwald’s Heart Disease textbook discusses the use of EECP as an alternative for refractory angina. Responses to the seven-week treatment have been reported to last up to two years. However, there are no definitive data that EECP reduces the extent of ischemia determined by myocardial perfusion imaging. Most of the evidence demonstrating favorable effects of EECP is from uncontrolled studies, and data from sham-controlled studies are few.

Campbell et al performed a study to evaluate systolic and diastolic blood pressure for patients undergoing EECP. The authors found that EECP improved systolic blood pressure (SBP) in patients with refractory angina. On average, EECP decreased SBP, on average, during treatment and follow-up but for patients with low baseline SBP (<110mm Hg), EECP increased SBP. The improvements in SBP may contribute to the clinical benefit of EECP.

Erdling et al published the results of a study on patients with refractory angina that under EECP to evaluate if outcome can be predicted by analyzing baseline factors. Eighty-six patients were treated and followed for two years. The authors determined that EECP is safe and effective for those suffering from refractory angina pectoris. It was most beneficial for patients suffering from severe angina (Class III-IV) while sustained response to therapy could not be verified among patients suffering from Class II angina pectoris.

March 2010 Update
Published registry studies also demonstrated improvement in erectile function. Erectile function was improved in a study of 120 men prospectively enrolled from 16 centers. Three of five 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. The non-comparative design of this study makes it difficult to draw conclusions on treatment efficacy. Preliminary studies from Asia are also reporting early results on use on the use of EECP to the lower extremities in the treatment of acute ischemic stroke. 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.

In a 2009 paper, McKenna et al report on a systematic review and economic analysis of EECP for the treatment of stable angina and heart failure. Four studies (one randomized controlled trial and three nonrandomized comparative studies) comparing EECP treatment with no treatment in adults with chronic stable angina were included in the analysis. This review included a study by Barsheshet, et al in which 25 patients (15 ECP and ten controls) were evaluated at the end of treatment. Similar to the previously review Schechter study, “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.” 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.

The Blue Cross and Blue Shield Association has also sent this policy to three academic medical centers for input. Results were mixed with some reviews concluding that this therapy is
investigational while others commented about potential use in those with angina not amenable to surgical interventions.

**February 2012 Update**

Braith et al, 2010, conducted a randomized sham-controlled study to investigate the extra-cardiac effects of EECP on peripheral artery flow mediated dilation on symptomatic patients with coronary artery disease (CAD). Forty-two symptomatic patients with CAD were randomized (2:1 ratio) to either 35 1-hr sessions of EECP (n=28) or Sham-EECP (n=14). Flow-mediated dilation of the brachial and femoral arteries was performed using ultrasound. Plasma levels of nitrate and nitrite (NOx), 6-keto prostaglandin F1α (PGF1α), endothelin-1 (ET-1), asymmetric dimethylarginine (ADMA), tumor necrosis factor–α (TNF-α), monocyte chemoattractant protein–1 (MCP-1), vascular cell adhesion molecule (sVCAM), C-reactive protein (hsCRP), and 8-Isoprostane (8-iso-PGF2α) were measured. EECP increased brachial (+51% vs. +2%) and femoral (+30% vs. +3%) artery flow mediated dilation, the nitric oxide turnover/production marker NOx (+36% vs. +2%) and PGF1α (+71% vs. +1%), while decreasing ET-1 (-25% vs. +5%) and the nitric oxide synthase inhibitor ADMA (-28% vs. +0.2%) in treatment vs. sham, respectively (all p<0.05). EECP decreased the pro-inflammatory cytokines TNF-α (-16% vs. +12%), MCP-1 (-13% vs. +0.2%), sVCAM-1 (-6% vs. +1%), hsCRP (-32% vs. +5%), and the lipid peroxidation marker 8-iso-PGF2α (-21% vs. +1.3%) in treatment vs. sham, respectively (all p<0.05). EECP reduced angina classification (-62% vs 0%; p<0.001) in treatment vs. sham, respectively. Their findings provide novel mechanistic evidence that EECP has a beneficial effect on peripheral artery flow mediated dilation and endothelial-derived vasoactive agents in patients with symptomatic CAD.

**February 2013 Update**

A small unblinded RCT published in 2012 addressed one health outcome, change after seven weeks in CCS angina class, along with multiple intermediate outcomes. 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 seven-week follow-up, soluble interleukin-2 receptor measurements significantly increased in the EECP group and significantly decreased in the no EECP group. There were no differences between groups at seven weeks in resting cutaneous microvascular blood flow or response to acetylcholine, sodium nitroprusside or local heating.

A 2012 Cochrane review of two RCTs of EECP in acute ischemic stroke concluded that the methodologic quality of the studies was poor and reliable conclusions could not be reached from this evidence.

**January 2014 Update**

The 2012 American College of Cardiology/American Heart Association (ACC/AHA) guidelines on the management of patients with stable ischemic heart disease indicate EECP “may be considered for relief of refractory angina.” This recommendation is based on Class IIb, Level of Evidence: B, which indicates the efficacy of the intervention is not well established and further studies would be helpful.
**Key Words:**
Enhanced external counterpulsation, EECP, external counterpulsation, ECP

**Approved by Governing Bodies:**
FDA 510(K) approval for treatment of angina and congestive heart failure.

"The EECP Therapy System Model TS3 with Pulse Oximetry is a noninvasive 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.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply  
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Special benefit consideration may apply. Refer to member’s benefit plan.  
Pre-certification requirements: Not applicable

**Current Coding:**
CPT code:  
92971 Cardioassist-method of circulatory assist; external

HCPCS code:  
G0166 External counterpulsation, per treatment session

**References:**


Policy History:
TEC, 1999(2)
Medical Review Committee, May 2000
Medical Review Group, May 2002
Medical Review Committee, June 2002
Medical Policy Administration Team, August 2002
Available for comment August 13-September 27, 2002
Medical Policy Group, July 2003
Medical Review Committee, August 2003
Medical Policy Administration Committee, September 2003
Available for comment October 7-November 20, 2003
Medical Policy Group, August 2005 (1)
Medical Policy Group, August 2007 (1)
Medical Policy Group, August 2009 (1)
Medical Policy Panel, February 2010
Medical Policy Group, March 2010 (2)
Medical Policy Administration Committee, April 2010
Available for comment April 7-May 21, 2010
Medical Policy Group, February 2012 (1): Update to Key Points and References; no change in policy statement
Medical Policy Panel, February 2013
Medical Policy Group, February 2013 (1): 2013 Update to Key Points and References; no change in policy statement
Medical Policy Panel January 2014
Medical Policy Group January 2014 (4): Updated Key Points, Approved Governing Bodies, and References. Removed policy section that was February 2010 and earlier, but there was no actual change to the policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.