BlueCross BlueShield of Alabama

Name of Policy:
Enhanced External Counterpulsation (EECP)

Policy #: 059
Category: Medical

Latest Review Date: May 2018
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 used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. It has been studied primarily as a treatment for patients with refractory angina and heart failure.

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

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

Policy:

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**
- **ONE** of the following
    1. The patient is not a candidate for a re-vascularization procedure such as percutaneous transluminal coronary angioplasty (PTCA), coronory 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
    2. 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,
- in lieu of a physician recommended revascularization procedure such as PTCA, coronory artery stenting, or CAGB
- erectile dysfunction ;

- Ischemic stroke

Angina Classification

Classification	NYHA	CCSC
O	Not applicable	Asymptomatic
I	Patients with no limitation of activities; they suffer no symptoms from ordinary activities	Angina with strenuous exercise
II	Patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion	Angina with moderate exertion
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:

The most recent literature review was performed through March 6, 2018.

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 one 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.

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 enhanced external counterpulsation (EECP) registries and case series, that have generally reported pre- and posttreatment measures of EECP effectiveness.

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 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.

Angina

Randomized Controlled Trials

In 1999, Arora et al presented results of the MUST-EECP trial. MUST-EECP applied a randomized controlled, double-blinded protocol that compared active treatment to placebo (inactive counterpulsation [CP] sham treatment) among 139 patients with Canadian Cardiovascular Society (CCS) Classification Scales (a functional assessment tool based on the level of exertion that elicits symptoms) class I-III chronic, stable angina. 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 >/= 1mm in the ST segment on electrocardiogram)

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

Intention-to-treat analyses were reported for the angina count and nitroglycerin usage outcomes only. There was a statistically significant difference (p=0.01) between groups in the change in time to 1mm or greater ST segment depression. Patients in the EECP group had an average difference of 37 seconds longer time to ST segment depression compared with the sham-treated group. The clinical significance of this is unknown. There was no significant difference between treatment groups in the change in exercise duration from baseline to the posttreatment period (p<0.31), angina counts (p<0.09) or nitroglycerin use (p>0.1).

A small unblinded RCT published in 2011 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 (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 seven 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. One such RCT (n=20) was published in 2010 comparing intracoronary blood flows in patients treated with EECP against those treated with a sham procedure. This trial was designed to detect statistically significant differences in collateral flow rates by angiography, not anginal symptoms. After seven weeks of treatment, collateral flow index increased significantly in the EECP group compared to sham treatment. Similar findings were noted in a comparative study by Buschmann et al of 23 patients published in 2009.

Two publications from a single study reported on blood flow and other measures of arterial function. This study 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 study also reported that measures of arterial stiffness were improved in the EECP group. Martin et al randomized 18 patients with abnormal glucose tolerance to EECP or standard care and reported that measures of glucose tolerance, as well as measures of arterial function, were improved in the EECP group.

In a randomized pilot study, Shakouri et al (2015) reported on intermediate outcome measures, including plasma nitric oxide (NO), endothelin 1, high sensitivity C reactive protein (HSCRP), and quality of life, in patients with coronary artery disease randomized to 20 sessions of EECP (n=21) or cardiac rehabilitation (n=21). There were no statistically significant improvements in physiologic markers and quality of life over time in both groups and no statistically significant differences between groups in change in any of the parameters evaluation.

Systematic Reviews

In 2009, 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 systematic review included a study by Barsheshet, et al (2008) in which 25 patients (15 EECP and ten controls) were evaluated at the end of treatment. Similar to the previously review Schechter study (2003), "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."

In 2010, Amin et al published a Cochrane review of major databases through 2008 on evidence of the effectiveness of EECP for chronic angina pectoris. The solitary RCT identified was the MUST-EECP trial. The authors of this review highlighted patient selection for this study. They noted that limiting the study population to patients with CCS class below IV diminishes the study's generalizability to patients of interest, that is, patients with the most severe symptoms of chronic angina pectoris.

Also in 2010, Shah et al 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. The MUST-EECP RCT was not included, as change in CCS class was not one of the reported outcomes. A total of 13 studies met these inclusion criteria (total N=949 patients). Overall, improvement of at least 1 level of angina class occurred in 86% of patients (95% confidence interval, 82% to 90%; p=0.008).

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.

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.

A 2016 systematic review and meta-analysis by Qin et al focused on the effect of EECP on intermediate measure of myocardial perfusion in patients with coronary artery disease. The systematic review 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 pooled analysis, EECP was associated with increased myocardial perfusion in CAD patients (pooled weighted mean difference [WMD] -0.19, 95% CI, -0.38 to 0.00, P=0.049).

Registry Studies

Registry-based studies have been published that report on relatively large numbers of patients. In a registry-based study by Soran (2007), 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.

Another registry-based study from the International Enhanced External Counterpulsation Patient [IECP] Registry, reported by Loh et al (2008), provided 3-year results on patients with chronic refractory angina. The registry enrolled 5000 patients from 99 U.S. and 9 international centers between 1999 and 2001. However, analysis was completed only for those centers that had at least 80% compliance with follow-up data submission; the study reported results on 1427 patients. In this selective 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/IV) were reduced from 89% to 25% ($p<0.001$). This was sustained in 74% of the patients during follow-up. More severe baseline angina and a history of heart failure or diabetes were independent predictors of unfavorable outcome.

Observational Studies

Numerous individual observational studies have been detailed in previous reviews and are included in systematic reviews previously described. For example, 2 prospective cohort studies (n=55 and n=61) with 1-year outcomes have been reported. Improved CCS classification was the main reported outcome, which persisted for 1 year in 79% and 78% of patients in the respective studies. Both studies had higher rates of treatment completion and follow-up than the previously reported (registry) studies assessing long-term outcomes.

Heart Failure

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

The 2005 TEC Assessment included heart failure in the analysis and concluded the evidence supporting the role of EECP as an effective treatment for heart failure is lacking in both quantity

and quality. A single randomized, multicenter study of EECP compared to usual care in 187 optimally medically managed patients with New York Heart Association (NYHA) functional class II or III heart failure with an ejection fraction of 35% or less of ischemic or idiopathic etiology, the "Prospective Evaluation of EECP in Congestive Heart Failure" (PEECH trial), was mostly inconclusive. The design and methods of the PEECH trial were published by Feldman et al. The results of the PEECH trial found statistically improved, but modest, changes in exercise duration and improved functional classification but not in quality of life or peak oxygen uptake (VO2).

A subgroup analysis from the PEECH trial for heart failure was published in 2006. It showed that subjects aged 65 years and older treated with EECP (n=41) were more likely to meet the exercise duration (35% vs 25% increased by ≥60 seconds) and peak VO2 (30% vs 11% increased by ≥1.25 mL/kg/min) improvement thresholds compared to those undergoing sham treatment (n=45); there was no difference at six months in NYHA class. This poststudy analysis must be viewed as a preliminary result.

In 2015, Rampengan et al reported on a double-blinded randomized controlled trial evaluating EECP in patients with CHF treated in Indonesia. Patients with NYHA functional class I or II symptomatic heart failure from a variety of 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 mmHg of pressure, vs the standard 300 mmHg. Analysis was per protocol, excluding 6 and 7 patients who dropped out of the active and sham groups, respectively. Post-intervention, active EECP group patients were more likely to have a 6 minute walk test (6MWT) distance of 300 m or greater (98.0% vs 32.7%, P<0.01). The change in 6MWT distance was greater (improved) for the active EECP patients than for the sham control patients (192.6 vs -9 m, P<0.05).

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 on 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 Indications
The use of EECP for other conditions associated with ischemia or vascular dysfunction has been investigated. In 2009, Fraser and Adams produced a Cochrane review on interventions for central retinal artery occlusion (CRAO). One of the two RCTs identified compared hemodilution with EECP against hemodilution without further intervention. In the trial by Werner et al (2004), the EECP intervention was a single, two-hour treatment. According to the reviewers, in this study (n=20), patients were randomized but not blinded; no sham treatment was given. Primary outcomes were Doppler flowmetry of retinal perfusion and visual acuity.

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. A 2012 Cochrane by Lin et al assessed 2 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.

In 2016, Sardina et al reported on an RCT which randomized 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 and 6 months. At 6 months of follow up, patients in the EECP group had significant decreases over time in variety of biomarkers of advanced glycation end products, inflammation, and oxidative stress. At 6 months of follow up, the percent change in advanced glycation end products and receptor of advanced glycation end products differed significantly between groups ($P<0.05$).

Summary of Evidence

For individuals who have chronic stable angina who receive enhanced external counterpulsation (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 1 blinded randomized controlled trial (RCT) that includes clinical outcomes, and this trial reported benefit on only 1 of 4 main angina outcomes. Additional small RCTs have reported changes in physiologic measures associated with EECP. One systematic review reports a decrease in severe angina from 89% to 25% post EECP. The improvement was sustained during follow up.

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 reported a modest benefit with EECP on some outcomes and no benefit on others. A second RCT reported improvements on the 6 minute walk test with EECP. 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 the effects of the technology on health outcomes.

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 in 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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
The 2012 American College of Cardiology Foundation, American Heart Association, and 5 other medical societies stated in their guidelines that patients with stable ischemic heart disease indicate EECP "may be considered for relief of refractory angina." (Class IIb, Level of Evidence B)

In 2014, the ACCF/AHA issued a Focused Update on the 2012 guideline on the diagnosis and management of patients with stable ischemic heart disease in which they specifically reviewed their recommendation on EECP. Based on their review, the recommendation on EECP remains unchanged from the 2012 guideline.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (USPSTF) has not addressed enhanced external counterpulsation.

Key Words:
Enhanced external counterpulsation, EECP, external counterpulsation, ECP, angina, congestive heart failure, CHF

Approved by Governing Bodies:
A variety of enhanced external counterpulsation (EECP) devices have been cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. Examples of EECP devices with FDA clearance are outlined in Table 1.

Table 1: FDA-Cleared EECP Devices

Device	Manufacturer	Clearance Date	Indications
Renew® NCP-5 External Counterpulsation System	Renew Group (Rockville, MD)	December 2015	• Treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. • For use in healthy patients to provide improvement in vasodilation, increased VO2, and increased blood flow.
ECP Health System Model	ECP Health	August 2005	• Stable or unstable angina pectoris • Acute myocardial

			infarction • Cardiogenic shock • Congestive Heart Failure
CardiAssist™ Counter Pulsation System	Cardiomedics (Irvine, CA)	March 2005	• Treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, MI, and cardiogenic shock
ACS Model NCP- 2 External Counterpulsation Device	Applied Cardiac Systems (Laguna Hills, CA)	August 2004	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive Heart Failure
EECP® Therapy System	Vasomedical (Westbury, NY)	March 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

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: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT code:

92971 Cardioassist-method of circulatory assist; external
93041 Rhythm EKG, one to three leads; tracing only without interpretation and reports

HCPCS code:

G0166 External counterpulsation, per treatment session

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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.
Medical Policy Panel, January 2015
Medical Policy Group, January 2015 **(4):** Updates to Description, Key Points, Approved Governing Bodies, Coding section and References. No policy statement change.

Medical Policy Panel, August 2016
Medical Policy Group, August 2016 **(4):** Updates to Key Points, Approved Governing Bodies, and References. No change to policy statement.
Medical Policy Panel, October 2017
Medical Policy Group, October 2017 **(4):** Updates to Key Points and References. No change to policy statement.
Medical Policy Panel, May 2018
Medical Policy Group, May 2018 **(4):** Updates to Description and Key Points. No change to policy statement.
