Policy Statement

Enhanced external counterpulsation is considered investigational for all indications, including but not limited to:

I. Erectile dysfunction
II. Heart failure
III. Ischemic stroke
IV. Treatment of chronic stable angina pectoris

NOTE: Refer to Appendix 1 to see the policy statement changes (if any) from the previous version.

Policy Guidelines

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

Coding

EECP may be coded using a series of CPT codes describing the individual components of the procedure (see the Coding section).

The following HCPCS code is specific to EECP:

- G0166: External counterpulsation, per treatment session

Description

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

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.
Regulatory Status

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

Table 1. FDA-Cleared EECP Devices

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

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

Rationale

Background
Enhanced external counterpulsation (EECP) uses timed, sequential inflation of pressure cuffs on the calves, thighs, and buttocks to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. The proposed mechanism of action is the augmentation of diastolic pressure by displacement of a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and resistance in the coronary arteries is at a minimum. The resulting increase in coronary artery perfusion pressure may enhance coronary collateral development or increase flow through existing collaterals. Also, when the left ventricular contracts, it faces reduced aortic counterpressure, because the counterpulsation has somewhat emptied the aorta. EECP has been primarily investigated as a treatment for chronic stable angina.

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

**Literature Review**

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

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

**Chronic Stable Angina**

**Clinical Context and Therapy Purpose**

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

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

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

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

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

Patients with stable angina are actively managed by cardiologists in an outpatient clinical setting.

**Comparators**
Comparators of interest include guideline-directed medical management.

Patients with stable angina are actively managed by cardiologists in an outpatient clinical setting.
**Outcomes**
The general outcomes of interest are overall survival (OS), symptoms, morbid events, and functional outcomes.

Available literature has followed patients for up to 3 years, but in practice, patients with chronic stable angina would be followed by cardiologists for the rest of their lives.

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

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

**Review of Evidence**
**Randomized Controlled Trials**
Arora et al (1999) presented results of the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP) trial. The MUST-EECP trial applied a randomized controlled, double-blinded protocol that compared active treatment with placebo (inactive counterpulsation sham treatment) among 139 patients with Canadian Cardiovascular Society (CCS) Classification Scales (a functional assessment tool based on the level of exertion that elicits symptoms) class I, II, or III chronic, stable angina. Four outcomes were examined: (1) self-reported frequency of angina, analyzed 2 ways; (2) self-reported use of on-demand nitroglycerin; (3) exercise duration tolerance testing; and (4) time to exercise-induced ischemia (defined as time to depression of ≥ 1 mm in the ST segment on an electrocardiogram).

All patients underwent the same 35-hour protocol, followed by an exercise tolerance test within 1 week of completing therapy. Follow-up beyond the treatment period was not conducted. Intention-to-treat analyses were reported for the angina count and nitroglycerin usage outcomes only. There was a statistically significant difference (P = .01) between groups in the change in time to ≥ 1 mm or greater ST-segment depression. Patients in the EECP group had an average difference of 37 seconds longer time to ST-segment depression than the sham-treated group. There was no significant difference between treatment groups in the change in exercise duration from baseline to the posttreatment period (P < .31). Also, there were no statistically significant differences between groups concerning angina counts (P < .09) or nitroglycerin use (P > .1).

In addition to methodologic limitations found in the design, execution, and reporting of this trial, the magnitude of the benefit reported was not large. Of the 4 endpoints of interest, only time to ST-segment depression differed statistically in the EECP group compared with the sham group. The clinical significance of a 37-second improvement in time to ST-segment depression is unknown, but because it occurred while the other 3 endpoints were statistically unchanged with therapy should not suggest that this anomaly marks improvement. That both groups showed increased exercise duration suggests a degree of placebo effect; exercise duration possesses a motivational component that time to ST-segment depression does not.
Arora et al (2002) published a 12-month follow-up to the MUST-EECP trial. Only 71 (54%) of the original 139 subjects in the study. Subjects treated with EECP reported greater improvement in several quality of life scales. However, such findings could not be correlated with treatment responses reported in the first study (because of data limitations). The findings were further limited by the small sample size and a potentially biased sample of the original subject pool.

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

Additional RCTs have reported on intermediate, or physiologic, outcomes. Gloekler et al (2010) published one such RCT (N = 20), which compared intracoronary blood flows in patients treated using EECP with those treated using a sham procedure. This trial was designed to detect statistically significant differences in collateral flow rates by angiography, not anginal symptoms. After 7 weeks of treatment, collateral flow index increased significantly in the EECP group and compared with sham treatment. Buschman et al (2009) noted similar findings in a comparative study et al (2009) of 23 patients.

Two publications reported on a single trial evaluating blood flow and other measures of arterial function. This trial randomized 42 patients with coronary artery disease and chronic angina to EECP or sham EECP. EECP improved flow-mediated dilation in the brachial and femoral arteries and improved numerous serum markers of blood flow and inflammation. The same trial also reported that measures of arterial stiffness were improved in the EECP group.

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

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

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

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

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

Shah et al (2010) published a meta-analysis of prospective studies, not limited to RCTs, of EECP in stable angina in which CCS class was adequately reported before and after treatment. The MUST-EECP RCT was not included because the change in CCS class was not a reported outcome. Thirteen studies met these inclusion criteria (total N=949 patients). Overall, improvement of at least 1 level of angina class occurred in 86% of patients (95% CI, 82% to 90%; P =0.008). No conclusions can be drawn from this analysis given the lack of randomization (comparison group) for most studies analyzed.

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

Qin et al (2016) published a systematic review and meta-analysis that focused on the effect of EECP on the intermediate measure of myocardial perfusion in patients with coronary artery disease. Reviewers included 6 studies reporting on myocardial perfusion or coronary flow outcomes published from 1992 to 2007, including 5 RCTs and 1 prospective, observational, blinded study. In the pooled analysis, EECP was associated with increased myocardial perfusion in patients with coronary artery disease (pooled weighted mean difference = -0.19; 95% CI, -0.38 to 0.00; P =0.049).

Registry Studies
Registry-based studies have reported on relatively large numbers of patients. Soran et al (2007) conducted a study on 450 patients with left ventricular dysfunction (ejection fraction, ≤ 40%) and refractory angina who 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. Drawing conclusions from this study is not possible due to lack of a comparison group.

Loh et al (2008) reported on another study from the International Enhanced External Counterpulsation Patient Registry (2008), providing 3-year results for patients with chronic refractory angina. The registry enrolled 5000 patients from 99 U.S. and 9 international centers between 1999 and 2001. However, this analysis was completed only for those centers that had at least 80% compliance with follow-up data submission; the study reported results on 1427 patients. In this select group, 220 (15.4%) patients died, while 1061 (74.4%) patients completed their follow-up. Immediately post-EECP, the proportion of patients with severe angina (CCS class III or IV) was reduced from 89% to 25% (P<0.001). This improvement was sustained in 74% of the patients during follow-up. More severe baseline angina and a history of heart failure or diabetes were independent predictors of unfavorable outcome. Again, the lack of a control group in this study precludes drawing conclusions about this technology.
The International Enhanced External Counterpulsation Patient Registry data have also been examined to determine the safety and efficacy of EECP in patients with peripheral arterial disease (PAD). PAD, while a common comorbidity of coronary artery disease, has been regarded as a contraindication to EECP due to concerns about compression on peripheral blood flow and a potentially greater risk of aortic rupture. Thakkar et al (2010) compared registry data in patients who had PAD with those who did not. Based on a reduction of 1 or more CCS angina classes, patients with PAD had a similar rate of improvement as did the group without PAD (76.6% vs. 79.0%, respectively; P=.27). Rates of hospitalization for all cardiac causes (6.1% vs. 4.4%, respectively; P=.17) and for unstable angina (5.4% vs. 3.5%, respectively; P=.25) were also similar between groups.

Observational Studies
Numerous individual observational studies have been detailed above and are included in systematic reviews previously described. 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 was maintained for 1 year in 79% and 78% of patients in the respective studies. Both studies had higher rates of treatment completion and follow-up than the previously reported (registry) studies assessing long-term outcomes.

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

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

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

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

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

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

Patients with heart failure are actively managed by cardiologists in an outpatient clinical setting.

Comparators
Comparators of interest include guideline-directed medical management.

Patients with heart failure are actively managed by cardiologists in an outpatient clinical setting.
Outcomes
The general outcomes of interest are OS, symptoms, morbid events, and functional outcomes.

The limited available literature has followed patients for up to 6 months, but in practice, patients with heart failure would be followed by cardiologists for the rest of their lives.

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

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

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

A 2006 subgroup analysis of the PEECH trial showed that subjects aged 65 years and older treated with EECP (n = 41) were more likely to meet the exercise duration (35% vs. 25% increased by ≥ 60 seconds) and peak oxygen consumption (30% vs. 11% increased by ≥ 1.25 mL/kg/min) improvement thresholds compared with those undergoing sham treatment (n = 45); there was no difference at 6 months in NYHA class.

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

Similar to the registry evidence for EECP for angina, registry studies for heart failure have provided relatively little insight into the comparative efficacy of EECP. Soran et al (2002) conducted a single-arm study indicating that patients showed some improvements, but the lack of a comparison arm precluded inferences about the true effects of therapy.

Reproduction without authorization from Blue Shield of California is prohibited
McKenna et al (2009), in their previously described review, included the only trial of EECP for heart failure available at that time, the 2006 PEECH study. Reviewers concluded that the studies did not provide firm evidence of the clinical effectiveness of EECP in heart failure and that high-quality studies would be required to investigate the benefits of EECP and whether they outweigh the common adverse events.

Section Summary: Heart Failure
The evidence for the use of EECP in heart failure includes 2 RCTs that reported on clinical outcomes. One study reported modest improvements for some outcomes and none for others. A second study reported improvements in the 6-minute walk test but had methodologic limitations that, in turn, limited the conclusions that could be drawn from the study. The observational studies added little to the evaluation of efficacy due to the variable natural history of heart failure, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect. Further high-quality RCTs would be needed to determine whether EECP is a useful treatment for heart failure.

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

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

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

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

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

Patients with other indications related to ischemia or vascular dysfunction are actively managed by cardiologists in an outpatient clinical setting.

Comparators
Comparators of interest include guideline-directed medical management.

Patients with other indications related to ischemia or vascular dysfunction are actively managed by primary care physicians and cardiologists in an outpatient clinical setting.

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

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

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

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

**Review of Evidence**

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

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

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

Sardina et al (2016) reported on an RCT that allocated 30 patients with type 2 diabetes in a 2:1 ratio to EECP (n = 20) or standard care for diabetes (n = 10), and reported results out to 3 and 6 months. At 6-month follow-up, patients in the EECP group had significant decreases in a variety of biomarkers of advanced glycation end products, inflammation, and oxidative stress; the percent change in advanced glycation end products and receptor of advanced glycation end products differed significantly between groups (P<0.05).

**Summary of Evidence**

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

For individuals who have heart failure who receive EECP, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. One RCT that reported on clinical outcomes found a modest benefit with EECP on some outcomes but not others. A second RCT reported improvements on the 6-minute walk test with EECP but had methodologic limitations; RCT findings ultimately proved inconclusive. The observational studies on EECP in heart failure have limited ability to inform the evidence on EECP due to the multiple confounding variables for cardiac outcomes and the potential for a placebo effect. The evidence is insufficient to determine 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 EECP, but design shortcomings limit conclusions drawn. EECP has also been used to treat acute ischemic stroke, but the evidence base is not robust. EECP has been used in a small RCT to treat type 2 diabetes. Reported follow-up was short-term. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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

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

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

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Medicare has published a national coverage decision on EECP that mandates coverage for the following indications 43:

“Coverage is provided for the use of ECP [external counterpulsation] for patients who have been diagnosed with disabling angina who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty or cardiac bypass because: 1) Their condition is inoperable, or at high risk of operative complications or post-operative failure; 2) Their coronary anatomy is not readily amenable to such procedures; or 3) They have co-morbid states which create excessive risk.”

Medicare’s coverage decision also noted that while the U.S. Food and Drug Administration has cleared EECP for use in treating a variety of cardiac conditions, including stable or unstable
angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered...."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>An Open-label Study to Evaluate the Effects of Enhanced External Counterpulsation on Tapering Inotropic Agents, Reduction of Brain Natriuretic Peptide and Rehospitalization of Patients With Heart Failure</td>
<td>40</td>
<td>Nov 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

References


**Documentation for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>92971</td>
<td>Cardioassist-method of circulatory assist: external</td>
</tr>
<tr>
<td>HCPCS</td>
<td>G0166</td>
<td>External counterpulsation, per treatment session</td>
</tr>
</tbody>
</table>

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/14/1998</td>
<td>New Policy Adoption</td>
</tr>
<tr>
<td>10/22/1999</td>
<td>Policy Review</td>
</tr>
<tr>
<td>08/01/2002</td>
<td>Coding Update</td>
</tr>
<tr>
<td>10/16/2002</td>
<td>Policy Title Revision, criteria revised</td>
</tr>
<tr>
<td>03/01/2006</td>
<td>Policy Name Change</td>
</tr>
<tr>
<td>06/28/2007</td>
<td>Policy Revision</td>
</tr>
<tr>
<td>06/26/2009</td>
<td>Policy Revision</td>
</tr>
<tr>
<td>07/02/2010</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>06/28/2013</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>07/31/2015</td>
<td>Policy title change from Enhanced External Counterpulsation (EECP)</td>
</tr>
<tr>
<td>10/01/2016</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>12/01/2017</td>
<td>Policy revision with position change effective 02/01/2018</td>
</tr>
<tr>
<td>02/01/2018</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>07/01/2018</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>07/01/2019</td>
<td>Policy revision without position change</td>
</tr>
</tbody>
</table>
Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.
### POLICY STATEMENT

#### BEFORE

<table>
<thead>
<tr>
<th>Enhanced External Counterpulsation 2.02.06</th>
</tr>
</thead>
</table>

**Policy Statement:**
Enhanced external counterpulsation is considered *investigational* for all indications, including but not limited to:

I. Erectile dysfunction
II. Heart failure
III. Ischemic stroke
IV. Treatment of chronic stable angina pectoris

#### AFTER

<table>
<thead>
<tr>
<th>Enhanced External Counterpulsation 2.02.06</th>
</tr>
</thead>
</table>

**Policy Statement:**
Enhanced external counterpulsation is considered *investigational* for all indications, including but not limited to:

I. Erectile dysfunction
II. Heart failure
III. Ischemic stroke
IV. Treatment of chronic stable angina pectoris