2.02.06	Enhanced External Counterpulsation		
Original Policy Date:	October 14, 1998	**Effective Date:**	July 1, 2024
Section:	2.0 Medicine	**Page:**	Page 1 of 15

Policy Statement

I. Enhanced external counterpulsation is considered **investigational** for all indications, including but not limited to:
   A. Erectile dysfunction
   B. Heart failure
   C. Ischemic stroke
   D. Treatment of chronic stable angina pectoris

NOTE: Refer to Appendix A 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
See the Codes table for details.

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 individuals 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

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

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

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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 individuals with chronic stable angina.

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

Populations

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

Interventions

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

Comparators

Comparators of interest include guideline-directed medical management.

Outcomes

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

Available literature has followed patients for up to 3 years.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

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

Review of Evidence

Randomized Controlled Trials

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

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

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

Arora et al (2002) published a 12-month follow-up to the MUST-EECP trial.[2,] Only 71 (54%) of the original 139 subjects in the study were included. Subjects treated with EECP reported greater improvement in several quality of life scales. However, such findings could not be correlated with treatment responses reported in the first study (because of data limitations). The findings were further limited by the small sample size and a potentially biased sample of the original subject pool.

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

Additional RCTs have reported on intermediate or physiologic outcomes. Gloekler et al (2010) published one such RCT (N=20), which compared intracoronary blood flow in patients treated using EECP with those treated using a sham procedure.[4,] This trial was designed to detect statistically significant differences in collateral flow rates by angiography, not anginal symptoms. After 7 weeks of treatment, collateral flow index increased significantly in the EECP group compared with sham treatment. Buschman et al (2009) noted similar findings in a comparative study et al (2009) of 23 patients.[5,]

Two publications reported on a single trial evaluating blood flow and other measures of arterial function.[6,7,] This trial randomized 42 patients with coronary artery disease and chronic angina to EECP or sham EECP. EECP improved flow-mediated dilation in the brachial and femoral arteries and improved numerous serum markers of blood flow and inflammation. The same trial also reported that measures of arterial stiffness were improved in the EECP group.

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

Systematic Review

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

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

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

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 individuals with heart failure. The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with heart failure.

Interventions

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

Comparators

Comparators of interest include guideline-directed medical management.

Outcomes

The general outcomes of interest are OS, symptoms, morbid events, and functional outcomes. The limited available literature has followed patients for up to 6 months..

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

The 510(k) approval of the Vasomedical devices stated that objective measures, such as peak oxygen consumption, exercise duration, and preload-adjusted maximal left ventricular power, are improved following EECP therapy, as are subjective measures of patient response to therapy, such as quality of life and functional ability.[12,] However, no clinical details of these studies were provided in the U.S. Food and Drug Administration (FDA) summary, and these data were not from controlled trials.

The 2005 TEC Assessment included heart failure in its analysis and concluded the evidence supporting the role of EECP as an effective treatment for heart failure was lacking in both quantity and quality.[9,] A single randomized, multicenter study 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.[13,] 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.[12,]Feldman et al (2006) also reported on the PEECH trial results indicating statistically improved, but modest, changes in exercise duration and improved functional class but not in quality of life or peak oxygen consumption.[13,]

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.[14,]

Rampengan et al (2015) reported on a double-blinded RCT evaluating EECP in patients with congestive heart failure treated in Indonesia.[15,] 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 mmHg of pressure versus the standard 300 mmHg. 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).

A small, open-label, ongoing RCT conducted in Russia by Belenkov et al (2024) randomized patients with ischemic heart disease and heart failure to optimal drug therapy alone (n=40), optimal drug therapy plus 1 course of EECP per year (n=40), or optimal drug therapy plus 2 courses of EECP per year (n=40).[16,] The total duration is anticipated to be 3 years. At 12 months, the percentage of patients achieving at least a 20% increase in 6-minute walk test was greater in the EECP groups than optimal drug therapy alone (97.5% and 72.5% vs 7.7%). Longer-term follow-up from this ongoing study may help clarify the role of EECP; however, the open-label nature and limited sample size of the study will limit the applicability of the findings.

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.[17,18,19,20,] 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.[21,]

McKenna et al (2009), in their previously described review,[22,] included the only trial of EECP for heart failure available at that time, the 2006 PEECH study.[13,] Reviewers concluded that the studies did not provide firm evidence of the clinical effectiveness of EECP in heart failure and that high-quality studies would be required to investigate the benefits of EECP and whether they outweigh the common adverse events.

Section Summary: Heart Failure

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

Other Conditions Related to Ischemia or Vascular Dysfunction

Clinical Context and Therapy Purpose

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

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

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

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

Comparators
Comparators of interest include guideline-directed medical management.

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

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

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

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

Review of Evidence
The use of EECP for other conditions associated with ischemia or vascular dysfunction has been investigated. Lin et al 2023 evaluated interventions for central retinal artery occlusion in a Cochrane review.[23,] The authors identified one prospective study [24,] that failed to find benefit in retinal reperfusion or visual acuity when EECP was added to hemodilution.

Published registry studies have also demonstrated improvements in erectile function. Lawson et al (2007) showed improved erectile function in a study of 120 men prospectively enrolled from 16 centers.[25,] 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.[26,]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.[27,]

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[28,] and 6 months.[29,] At 6-month follow-up, patients in the EECP group had significant decreases in a variety of biomarkers of advanced glycation end products, inflammation, and oxidative stress; the percent change in advanced glycation end products and receptor of advanced glycation end products differed significantly between groups ($p<.05$). Nagendra et al (2023) compiled the 12-week results of Sardina et al (2016) with 2 smaller RCTs (N=71) in patients with prediabetes or type 2 diabetes.[30,] Patients received standard diabetic care and were randomized to EECP or

placebo/passive control. Although improvements in hemoglobin A1c with EECP were noted at 7 to 12 weeks after therapy completion (mean difference, -0,98%; 95% CI, -1.22 to -0.74; p<.00001), there was high risk of detection and other biases. This, along with the small number of enrolled patients, short duration of follow-up, and unclear standard of care, limits the application of these findings.

Section Summary: Other Conditions Related to Ischemia or Vascular Dysfunction

An RCT assessed use of EECP for treatment of central retinal artery occlusion and failed to find clinical benefit.. 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 several small RCTs to treat type 2 diabetes. Reported follow-up was short-term, and trials had methodologic limitations.

Supplemental Information

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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

Practice Guidelines and Position Statements

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

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

In 2012, the American College of Cardiology Foundation, American Heart Association, and 5 other medical societies published joint guidelines that recommended: "[patients with stable ischemic heart disease who indicate for enhanced external counterpulsation (EECP)] may be considered for relief of refractory angina." This recommendation was class IIb, based on level B evidence (i.e., the efficacy of the intervention is not well established, and further studies would be helpful).[31,]

In 2014, the American College of Cardiology Foundation and American Heart Association updated these joint guidelines. [32,] Based on this review, the groups did not change their recommendation on EECP from the 2012 guidelines.

The 2022 American College of Cardiology Foundation, American Heart Association, and Heart Failure Society of America guidelines on the management of heart failure do not address EECP. [33,].

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[34]:

"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 amendable 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 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05913778	Long-term Effects of Enhanced External Counterpulsation on the Structural and Functional State of Blood Vessels in Patients With Coronary Heart Disease and Chronic Heart Failure	100 (actual)	Dec 2024

NCT: national clinical trial.

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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.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements

are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	92971	Cardioassist-method of circulatory assist; external
HCPCS	G0166	External counterpulsation, per treatment session

Policy History

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

Effective Date	Action
10/14/1998	New Policy Adoption
10/22/1999	Policy Review
08/01/2002	Coding Update
10/16/2002	Policy Title Revision, criteria revised
03/01/2006	Policy Name Change Policy position unchanged
06/28/2007	Policy Revision
06/26/2009	Policy Revision
07/02/2010	Policy revision with position change
06/28/2013	Policy revision with position change
07/31/2015	Policy title change from Enhanced External Counterpulsation (EECP) Policy revision without position change
10/01/2016	Policy revision without position change
12/01/2017	Policy revision with position change effective 02/01/2018
02/01/2018	Policy revision with position change
07/01/2018	Policy revision without position change
07/01/2019	Policy revision without position change
07/01/2020	Annual review. No change to policy statement. Literature review updated.
12/01/2020	Coding update.
07/01/2021	Annual review. No change to policy statement. Literature review updated.
07/01/2022	Annual review. No change to policy statement. Literature review updated.
07/01/2023	Annual review. No change to policy statement. Literature review updated.
07/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.

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 and Feedback (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.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Enhanced External Counterpulsation 2.02.06 **Policy Statement:** I. Enhanced external counterpulsation is considered **investigational** for all indications, including but not limited to: A. Erectile dysfunction B. Heart failure C. Ischemic stroke D. Treatment of chronic stable angina pectoris	**Enhanced External Counterpulsation 2.02.06** **Policy Statement:** I. Enhanced external counterpulsation is considered **investigational** for all indications, including but not limited to: A. Erectile dysfunction B. Heart failure C. Ischemic stroke D. Treatment of chronic stable angina pectoris