Clinical Policy Title: External counterpulsation (ECP) therapy

Clinical Policy Number: 04.02.03

Effective Date: July 1, 2015
Initial Review Date: February 18, 2015
Most Recent Review Date: March 15, 2017
Next Review Date: March 2018

Related policies:

CP# 04.02.01  Wearable cardioverter-defibrillators
CP# 04.02.02  Cardiac rehabilitation

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of external counterpulsation (ECP) to be clinically proven and, therefore, medically necessary when all of the following criteria are met:

- The individual has been diagnosed with disabling (Class III or IV of the Canadian Cardiovascular Society Classification or equivalent classification) chronic stable angina pectoris.
- A cardiologist or cardiothoracic surgeon has determined that the individual is not an appropriate candidate for surgical intervention (e.g., balloon angioplasty, cardiac bypass surgery) because of any of the following:
  - The individual's condition is inoperable.
  - The individual is at high risk of operative complications or postoperative failure.
  - The individual's coronary anatomy is not readily amenable to such procedures.
  - The individual has comorbid states that create excessive risk.
- A single course of one-hour treatments of up to 35 sessions is provided. Treatment may be offered once or twice daily, up to five days per week.
Limitations:

All other uses of ECP are not medically necessary.

Continued treatment beyond a single course of 35 sessions is not medically necessary, as there is insufficient evidence of a health benefit of extended ECP treatment.

Hydraulic versions of these devices are not medically necessary.

ECP is contraindicated in individuals with:

- Cardiac catheterization two weeks before or after the procedure (risk of bleeding at the femoral puncture site).
- Arrhythmia (risk of interference with the device’s triggering mechanism).
- Severe congestive heart failure (CHF) with ejection fraction less than 30 percent (risk of increased venous return adversely affecting hemodynamics).
- Aortic insufficiency (risk of regurgitation preventing diastolic augmentation).
- Peripheral vascular disease or phlebitis (risk of thromboembolism).
- Severe hypertension, greater than 180/110 mm Hg (risk of treatment producing diastolic blood pressure above acceptable limits).
- Bleeding diathesis (risk of cuffs causing leg bleeding).

Considerations for the use of ECP include the following:

- Hypertension and elevated heart rates should be controlled before starting treatment.
- Heart failure should be stable before starting treatment.
- Patients at high risk of complications from increased venous return should be carefully chosen and monitored during treatment. Decreasing cardiac afterload by optimizing diastolic augmentation may help minimize increased cardiac filling pressures due to venous return.
- Patients with clinically significant valvular disease should be carefully chosen and monitored during treatment. Certain valve conditions, such as significant aortic insufficiency or severe mitral or aortic stenosis, may prevent the patient from obtaining benefit from diastolic augmentation and reduce cardiac afterload in the presence of increased venous return.

Note: The following CPT/HCPCS code is not listed in the Pennsylvania Medicaid fee schedule:

92971 - Cardioassist-method of circulatory assist; external

Alternative covered services:

- Pharmacotherapy.
- Coronary artery bypass grafting (CABG).
- Percutaneous coronary intervention (PCI).
- Spinal cord stimulation (SCS).

**Background**

Approximately 8.9 million Americans are living with symptomatic ischemic heart disease (IHD), and nearly 380,000 people die from it each year (Murphy, 2013). Angina pectoris (also called stable angina) is episodic chest pain or discomfort caused by ischemia to the heart muscle that occurs most often when one or more of the coronary arteries becomes narrowed or blocked with a buildup of plaque (AHA, 2015). Exertion or psychological stress usually precipitates the discomfort, and rest or sublingual nitroglycerin usually relieves it. Diagnosis is by symptoms, electrocardiogram (ECG), and myocardial imaging. Depending on the severity of the condition at presentation, patients with angina will be treated either medically or surgically (NHLBI, 2015).

An estimated one million Americans have chronic, symptomatic IHD resistant to medical therapy and unamenable to conventional revascularization surgery (Grise, 2009). This is often referred to as refractory angina. Patients with this form of angina have marked limitation of ordinary physical activity and may be unable to perform any ordinary physical activity without discomfort. Novel pharmacologics (e.g., ranolazine hydrochloride, L-arginine, nicorandil, ivabradine) and noninvasive treatments have been introduced to treat these individuals.

**ECP therapy:**

ECP therapy is a noninvasive prescription device used to assist the heart by applying positive or negative pressure to one or more of the body’s limbs in synchrony with the heart cycle (21CFR870.5225). In light of its noninvasive approach, there is growing interest in the use of ECP for treatment of IHD, particularly in patients with refractory angina.

ECP uses inflatable cuffs on the legs that are timed to inflate and deflate based on the individual’s heart rate and rhythm. Early models used a single set of pneumatic cuffs, but more recent models apply three sets around the calves, thighs and buttocks. Patients are monitored continuously using a finger plethysmogram and ECG, which are connected to a control and display console. ECP is provided on an outpatient basis with daily one-hour sessions for up to seven weeks (35 total hours of therapy).
The U. S. Food and Drug Administration (FDA) classifies ECP as Class II (special controls) devices intended for the treatment of persons with chronic stable angina refractory to optimal anti-angina medical therapy and without surgical options for revascularization. Class III (premarket approval) is required for all other intended uses, including but not limited to, unstable angina pectoris, acute myocardial infarction, cardiogenic shock and CHF (21CFR870.5225). Several ECP devices have been approved for clinical use (FDA, 2015).

The mechanism of action of ECP is not completely understood (Casey 2011). Several explanations have been proposed, such as enhanced diastolic flow, the possible collateralization of coronary vessels and an improvement in endothelial function. When timed correctly, the ECP is believed to increase the preload that fills the heart, increasing the cardiac output, and to decrease the afterload against which the heart has to pump, decreasing cardiac workload and oxygen consumption. The aortic pressure would increase while the heart is relaxing (during diastole), thereby increasing blood flow into the coronary arteries. Improvement in coronary blood flow would open pre-existing collateral vessels and increase shear stress, which would in turn stimulate growth factors and endothelial function, resulting in increased angiogenesis and perfusion and decreased ischemia. However, research findings have not been entirely consistent, suggesting extra-cardiac factors, such as altered peripheral vascular function, may be involved (Casey, 2011).

Searches

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 12, 2017. Search terms were: “counterpulsation”(MeSH) and "angina pectoris" (MeSH) or “heart disease”(MeSH) and free text terms “external counterpulsation therapy.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
Findings

Keystone First identified three systematic reviews, one cost-effectiveness analysis and two guidelines for this policy. The systematic reviews included two randomized controlled trials (RCTs), several uncontrolled studies and several large patient registry analyses. One RCT compared the effectiveness of ECP to sham treatment in adults with chronic, stable Canadian Cardiovascular Society (CCS) Grades I – III angina (Multicenter Study of Enhanced External Counterpulsation [MUST-EECP]; Arora, 1999; Arora, 2002). The other RCT compared the effectiveness of ECP to pharmacologic treatment in adults with chronic heart failure (prospective evaluation of enhanced external counterpulsation in CHF [PEECH] study; Feldman, 2006). Numerous published studies attempting to explain the mechanism of action of ECP were not included in this policy.

The majority of the published research addresses the short-term effectiveness of ECP in adults with chronic stable angina or refractory angina. There is less evidence regarding the use of ECP in the treatment of chronic heart failure, and little or no evidence regarding the use of ECP in patients with other cardiac conditions such as myocardial infarction, CHF, unstable angina or cardiogenic shock. Treatment protocols were similar across studies, generally involving one-hour treatment sessions, five days a week, for a total of 35 treatment sessions.

The overall quality of the evidence is low due to poor trial methods and incompleteness in reporting. The numerous exclusion criteria used in the RCTs restricted the numbers of participants with the most severe forms of the disorders of interest, thereby limiting the external validity and generalizability of the results to patients with the most severe symptoms. Observational studies included a broader range of patients with stable chronic angina classified as CCS Grades I – IV, but were retrospective and small and often lacked a comparison group. The lack of a control group made it difficult to determine the magnitude of the treatment effect and whether the effect was, in fact, due to the treatment or placebo.

The most commonly used treatment is Enhanced External Counterpulsation (EECP®) Therapy (Vasomedical Inc., Westbury, NY). This treatment uses a device that applies a proprietary timing mechanism to inflate three sets of cuffs to about 200 mm Hg on the calves, the lower and upper thighs, and the buttocks, sequentially compressing them during diastole and rapidly deflating just before systole. Vasomedical Inc. fully or partially supported the registries and most studies, and many authors were consultants, employees or funding recipients of the manufacturer.

ECP is a relatively safe procedure. Complications are primarily device-related such as bruising, pain, skin abrasion and blistering on the legs where the pneumatic cuffs are placed. More serious adverse events such as worsening of CHF, myocardial infarction (MI), angina, chest pain (silent ischemia), ECG changes, arrhythmia and pulmonary edema are rare.

There is sufficient evidence to support the use of ECP for patients with chronic stable angina who are not suitable candidates for surgical revascularization or angioplasty. A protocol of 35, one-hour daily treatments is associated with angina reduction, improved exercise tolerance and some aspects of...
health-related quality of life (HRQoL) in a majority of patients, but a placebo effect cannot be ruled out. Observational studies also found improvements in nitroglycerin use and myocardial perfusion. ECP is cost-effective if the observed HRQoL benefits are assumed to continue throughout a patient’s lifetime, but its long-term effects have not been studied adequately. Evidence-based guidelines acknowledge the uncertainty in the evidence base by making weak recommendations for its use in this population, because the benefits of ECP, particularly the potential improvement in HRQoL, outweigh its risks (McGillion, 2012; Fihn, 2012).

ECP is contraindicated in the following patients (Hayes Inc., 2008; Vasomedical Inc., 2015):

- Cardiac catheterization two weeks before or after the procedure (risk of bleeding at the femoral puncture site).
- Arrhythmia (risk of interference with the device’s triggering mechanism).
- Severe CHF with ejection fraction less than 30 percent (risk of increased venous return adversely affecting hemodynamics).
- Aortic insufficiency (risk of regurgitation preventing diastolic augmentation).
- Peripheral vascular disease or phlebitis (risk of thromboembolism).
- Severe hypertension, greater than 180/110 mm Hg (risk of treatment producing diastolic blood pressure above acceptable limits).
- Bleeding diathesis (risk of cuffs causing leg bleeding).

Vasomedical Inc. also cautions that hypertension and elevated heart rates should be controlled before starting treatment, and patients with heart failure should be stable before starting treatment. Patients at high risk of complications from increased venous return should be carefully chosen and monitored during treatment. Decreasing cardiac afterload by optimizing diastolic augmentation may help minimize increased cardiac filling pressures due to venous return. Patients with clinically significant valvular disease should be carefully chosen and monitored during treatment. Certain valve conditions, such as significant aortic insufficiency or severe mitral or aortic stenosis, may prevent the patient from obtaining benefit from diastolic augmentation and reduce cardiac afterload in the presence of increased venous return (Vasomedical Inc., 2015).

There is insufficient evidence to support the use of ECP for other patient populations.

Policy update:

We identified two new systematic reviews and meta-analyses. Qin (2016) found standard ECP therapy significantly increased myocardial perfusion in patients with coronary artery disease (CAD), which suggests a possible explanation for the observed physiologic improvements in angina pectoris and long-term left ventricular function after ECP therapy. Very low quality evidence suggests a possible role for ECP in treating patients with acute ischemic stroke (Lin, 2012). Both findings require confirmation from further research. Therefore, no policy changes are warranted at this time.
### Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Qin (2016)</td>
<td><strong>Key points:</strong></td>
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| Effects of ECP on myocardial perfusion | - Systematic review and meta-analysis of six prospective studies (109 total patients).  
- Overall quality: high with low risk of bias. Limited by significant statistically heterogeneous outcomes across studies and small sample sizes. No evidence of publication bias.  
- Standard ECP therapy (i.e., 35-36 one-hour sessions within a seven-week period) significantly increased myocardial perfusion in patients with CAD (pooled weighted mean difference [WMD] -0.19, 95% confidence interval [CI] -0.38 to 0.00, p = 0.049). |
| Lin (2012)     | **Key points:**                   |
| Acute ischemic stroke | - Systematic review and meta-analysis of two RCTs (160 total patients) comparing ECP (started within seven days of stroke onset) vs. sham treatment or no treatment, or ECP plus routine treatment vs. routine treatment alone.  
- Overall quality: very low.  
- ECP was associated with a significant increase in the number of participants whose neurological impairment improved, based on Modified Edinburgh-Scandinavian Stroke Scale (MESSS) or self-making criteria (risk ratio 1.75, 95% CI 1.37 to 2.23). Only one trial reported no adverse events.  
- Insufficient evidence. High-quality and large-scale RCTs are needed. |
| Amin (2010)    | **Key points:**                   |
| Cochrane review, Chronic stable angina | - Systematic review of one RCT (MUST-EECP).  
- Excluded were participants with CCS IV, unstable angina, overt CHF, a pacemaker or implantable defibrillator, deep vein thrombosis, bleeding diatheses and warfarin use, those with previous MI or CABG in the preceding three months or cardiac catheterization in the previous two weeks, unable to undergo a treadmill test, or enrolled in cardiac rehabilitation programs.  
- Overall quality: low. High risk of bias with incomplete reporting of the primary outcome, limited follow-up for the secondary outcomes and subsequent flawed statistical analysis.  
- Authors’ conclusions: Results represent only a subsection of the broader population with the disorder, are not generalizable and provide inconclusive evidence for the effectiveness of ECP therapy for chronic angina pectoris. |
| McKenna (2009) | **Key points:**                   |
| Chronic stable angina, CHF | - Systematic review of two RCTs (MUST-EECP, n = 139; PEECH), three nonrandomized studies comparing ECP and elective PCI and usual care, and one cost-effectiveness analysis (CEA).  
- Authors’ conclusions: Impact of ECP on mortality or major adverse cardiovascular events in angina or CHF is unknown. ECP is cost-effective if observed quality of life benefits are assumed to continue throughout a patient’s lifetime, but long-term effects of ECP are unclear. |
| Hayes (2008)   | **Key points:**                   |
| All cardiac indications | - Systematic review of two RCTs (MUST-EECP and PEECH), several uncontrolled studies and case series, and several registry analyses from International Enhanced External Counterpulsation Patient Registry (IEPR) and NHLBI Dynamic Registry of Coronary |
Interventions.

- Study inclusion criteria: previous revascularization procedures, unsuitable for either percutaneous transluminal coronary angioplasty (PTCA) or CABG at the time of enrollment; inclusion criteria for patient registries were very broad.
- Baseline differences across RCT groups with respect to the proportions of patients with previous PCI, CABG and MI.
- ECP device manufactured by Vasomedical Inc. used in most studies.
- RCT results:
  - Time to ≥1 mm ST segment depression (exercise-induced ischemia) increased 41 seconds with ECP vs. sham (95% confidence interval [CI] 9.10 – 73.90).
  - More individuals in the ECP group reported 50% improvement in angina symptoms vs. sham group.
  - Possible placebo effect contributing to symptomatic relief.
  - ECP increased exercise duration and significantly reduced heart failure symptoms, but no increase in peak oxygen consumption.
- Uncontrolled studies:
  - ECP improved myocardial perfusion on radionuclide exercise stress test scans, angina symptoms and nitroglycerin use in patients with stable angina, with few adverse effects, but magnitude of treatment effect unclear.
  - Correlation between degree of symptom relief and hemodynamic effects of ECP unclear.
  - ECP not clearly superior to PCI.
  - Benefits of ECP may persist for several years.
- No studies of unstable angina, cardiogenic shock or acute MI.
- Complications include bruising, pain, skin abrasion and blistering on the legs where the pneumatic cuffs are placed. More serious adverse events are relatively rare and include worsening of CHF, MI, angina, chest pain (silent ischemia), ECG changes, arrhythmia and pulmonary edema.
- Contraindications: cardiac catheterization within two weeks, arrhythmia, severe CHF with ejection fraction <30%; aortic insufficiency, peripheral vascular disease or phlebitis, severe hypertension (>180/110 mm Hg), bleeding diathesis and pregnancy.

References

Professional society guidelines/others:


Peer-reviewed references:


**CMS National Coverage Determination (NCD):**


**Local Coverage Determinations (LCDs):**

No LCDs as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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