External counterpulsation therapy

Clinical Policy ID: CCP.1161

Recent review date: 3/2025

Next review date: 7/2026

Policy contains: Chronic stable angina pectoris; external counterpulsation therapy; refractory angina.

AmeriHealth Caritas Next has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Next'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, on a case by case basis, by AmeriHealth Caritas Next 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. AmeriHealth Caritas Next'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. AmeriHealth Caritas Next's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Next will update its clinical policies as necessary. AmeriHealth Caritas Next's clinical policies are not guarantees of payment.

Coverage policy

External counterpulsation therapy is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (Virani, 2023; McGillion, 2012):

- The member 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 member is not an appropriate candidate for surgical intervention (e.g., balloon angioplasty, cardiac bypass surgery) because of any of the following reasons:
    - An inoperable condition.
    - High risk for operative complications or postoperative failure.
    - Coronary anatomy not readily amenable to such procedures.
    - Comorbidities that create excessive risk.

Limitations

All other uses of external counterpulsation are investigational/not clinically proven and, therefore, not medically necessary (Buschmann, 2018; Lin, 2012; Raeissadat, 2018).

Hydraulic versions of these devices are not medically necessary.

External counterpulsation is contraindicated in members with (Vasomedical Inc., 2017):

- 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 with ejection fraction less than 30% (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).
- Pregnancy.

Considerations for the use of external counterpulsation include the following (Vasomedical Inc., 2017):

- Hypertension and elevated heart rates should be controlled before starting treatment.
- Heart failure should be stable before starting treatment.
- Members at high risk for 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.
- Members 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.

Alternative covered services

- Pharmacotherapy.
- Coronary artery bypass grafting.
- Percutaneous coronary intervention.
- Spinal cord stimulation.
- Cognitive-behavioral self-management interventions.

Background

Approximately 5% to 10% of patients diagnosed with stable coronary artery disease are estimated to have refractory angina pectoris (Henry, 2014). 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.

External counterpulsation 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). External counterpulsation uses inflatable cuffs on the legs timed to inflate and deflate based

on the individual's heart rate and rhythm. Patients are monitored continuously using a finger plethysmogram and electrocardiogram connected to a control and display console. In light of its noninvasive approach, there is growing interest in external counterpulsation for treating ischemic heart disease, particularly in patients with refractory angina.

The U.S. Food and Drug Administration (2018) classifies external counterpulsation 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 congestive heart failure (21CFR870.5225). Several devices have been approved for clinical use.

Its mechanism of action is not completely understood. 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, external counterpulsation 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. Aortic pressure would increase during diastole, thereby increasing coronary artery perfusion. 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, extra-cardiac factors, such as altered peripheral vascular function, may be involved (Casey, 2011).

Findings

The American Heart Association/American College of Cardiology updated a guideline on the management of chronic coronary disease that recommends external counterpulsation for symptom relief in patients who remain symptomatic and without other therapeutic options. While data supporting this indication are limited and the intervention is infrequently used, there may be short-term quality of life benefits (Virani, 2023).

Evidence-based guidelines acknowledge the uncertainty in the evidence base by making weak recommendations for its use in this population, because the benefits, particularly the potential improvement in health-related quality of life, outweigh the risks (Virani, 2023; McGillion, 2012).

The systematic reviews included two randomized controlled trials, several uncontrolled studies, and several large patient registry analyses. One randomized controlled trial compared the effectiveness of external counterpulsation to sham treatment in adults with chronic, stable Canadian Cardiovascular Society Grades I – III angina (Arora, 1999, 2002). The other randomized controlled trial compared the effectiveness of external counterpulsation to pharmacologic treatment in adults with chronic heart failure (Feldman, 2006). Numerous published studies attempting to explain the mechanism of action of external counterpulsation were not included in this policy.

The published research in the systematic reviews addresses the short-term effectiveness of external counterpulsation in adults with chronic stable angina or refractory angina. There is limited evidence regarding its use in the treatment of chronic heart failure or for other cardiac conditions such as myocardial infarction, congestive heart failure, 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 randomized controlled trials 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 Canadian Cardiovascular Society 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.

A commonly used treatment is Enhanced External Counterpulsation (EECP®) Therapy (Vasomedical Inc., Westbury, New York). 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.

External counterpulsation 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 congestive heart failure, myocardial infarction, angina, chest pain (silent ischemia), electrocardiographic changes, arrhythmia, and pulmonary edema are rare.

There is sufficient evidence to support the use of external counterpulsation 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 in a majority of patients, but a placebo effect cannot be ruled out. Observational studies also found improvements in nitroglycerin use and myocardial perfusion (Amin, 2010; Lin, 2012; Qin, 2016).

External counterpulsation is contraindicated in the following patients (Vasomedical Inc., 2017):

- 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 with ejection fraction less than 30% (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).
- Pregnancy.

Vasomedical Inc. (2017) 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 for 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.

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

In 2017, we identified two new systematic reviews and meta-analyses. Qin (2016) found standard external counterpulsation therapy significantly increased myocardial perfusion in patients with coronary artery disease, which suggests a possible explanation for the observed physiologic improvements in angina pectoris and long-term left ventricular function after external counterpulsation therapy. Very low-quality evidence suggests a possible role 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.

In 2018, no policy changes are warranted.

In 2019, we added one individual study (n = 28 participants) of external counterpulsation therapy for augmenting cerebral perfusion in individuals with chronic severe internal carotid artery stenosis (Buschmann, 2018) and one narrative review of four studies comprising 177 participants who received 20 to 35 hours per week of external counterpulsation for treatment of erectile dysfunction (Raeissadat, 2018). This new evidence is insufficient to establish external counterpulsation as an effective treatment for these two indications. Therefore, no policy changes are warranted. The policy ID was changed from CP# 04.02.03 to CCP.1161.

In 2020, we identified no newly published, relevant literature to add to the policy.

In 2021, we updated the references and identified no newly published, relevant literature to add to the policy.

In 2022, we updated the references and identified no newly published, relevant literature to add to the policy.

In 2023, we updated the references and identified no newly published, relevant literature to add to the policy. We removed treatment limits from the policy.

In 2024, we updated the references and added a new guideline (Virani, 2023) and new literature that confirms previous findings of external counterpulsation therapy as a noninvasive intervention for refractory angina. We added pregnancy to the list of contraindications in the limitations section.

A systematic review of economic analyses attempted to establish the cost effectiveness of external counterpulsation applied for 35 continuous sessions (each session takes one hour). The authors identified three studies of variable quality that provided insufficient evidence to generalize the cost effectiveness to different country settings; additional research is needed to extrapolate its economic value (Rezapour, 2022).

In 2025, we updated the references and identified no newly published, relevant literature to add to the policy.

References

On February 16, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “counterpulsation” (MeSH), “angina pectoris” (MeSH), “heart diseases” (MeSH), and “external counterpulsation therapy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

2/2015: initial review date and clinical policy effective date: 7/2015

2/2017: Policy references updated.

2/2018: Policy references updated.

2/2019: Policy references updated. Policy ID changed.

2/2020: Policy references updated.

3/2021: Policy references updated.

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated. Coverage limitations modified.

3/2025: Policy references updated.