Medical Coverage Policy

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External Counterpulsation

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses external counterpulsation (ECP) for the treatment of chronic stable angina pectoris and for other conditions in adults.

Coverage Policy

A course of up to 35 sessions of external counterpulsation (ECP) is considered medically necessary for the treatment of chronic stable angina pectoris as defined by the Canadian Cardiovascular Society (CCS) Functional Classification III or IV or equivalent when BOTH of the following criteria are met:

- there is failure, contraindication or intolerance to pharmacological management
- the individual is not a candidate for angioplasty or revascularization **OR** has undergone angioplasty or revascularization and continues to be symptomatic

External counterpulsation for ANY other indication including, but not limited to, the following is considered experimental, investigational or unproven:

- arrhythmia
- aortic insufficiency

- congestive heart failure
- erectile dysfunction
- fatigue/malaise
- hepatorenal syndrome
- long COVID syndrome (Post COVID)
- microvascular angina (cardiac syndrome X)
- peripheral vascular disease or phlebitis
- restless leg syndrome
- retinal artery occlusion
- severe hypertension (>180/100 mm Hg)
- stroke
- sudden deafness and tinnitus
- unstable angina
- vertebrobasilar insufficiency

General Background

External counterpulsation (ECP), also known as enhanced external counterpulsation (EECP), has been proposed as a noninvasive procedure that seeks to improve cardiovascular functioning in patients with chronic stable angina pectoris whom are refractory to medical and/or surgical management. ECP involves the sequential inflation of three sets of lower-extremity cuffs during diastole, leading to increased venous return and cardiac output, systolic unloading, and augmentation of the coronary artery perfusion pressure. The precise mechanisms accounting for the clinical benefits of ECP are not completely understood but include improved endothelial function, reduced aortic impedance, enhanced coronary artery collateral blood flow, and improved hemodynamics. The immediate hemodynamic effects of ECP are similar to intra-aortic balloon pump counterpulsation (Campbell, et al., 2008; Michaels, et al., 2006; Arora, et al., 1999).

A full course of ECP typically involves five hours of treatment per week, delivered in one- to two-hour sessions for seven weeks, for a total of 35 hours of treatment (Brosche, et al., 2004; Arora, et al., 1999). Michaels et al. (2005a) assessed the frequency, efficacy, predictors, and long-term success of repeat ECP therapy in relieving angina in a large cohort of patients who had chronic angina and had undergone a full course of ECP. Patients who underwent repeat ECP did benefit from the two courses of therapy, but they did not sustain the symptomatic improvement. Of the patients who had repeat ECP, 59% also had class 0 to II angina compared with 82% of those who did not undergo repeat ECP ($p<0.001$). Nitroglycerin use was more common in patients who underwent repeat ECP (63%) than in those who did not (45%; $p<0.0001$).

The reported adverse events or side effects that have been related to ECP therapy include leg or waist pain, skin abrasion or ecchymoses, bruises in patients using Coumadin when INR dosage is not adjusted, paresthesias, worsening of congestive heart failure (CHF) in patients with severe arrhythmia, myocardial infarction (MI), angina, chest pain, arrhythmia, and pulmonary edema (Manchanda, et al., 2007).

ECP is generally considered safe in patients without specific contraindications. According to the manufacturer's technical and professional guides for ECP therapy, the following conditions are considered precautions or contraindications to ECP therapy (Cardiomedics, 2019; Vasomedical, 2017):

- abdominal aortic aneurysm
- severe aortic regurgitation/severe aortic valve disorder
- phlebitis
- deep vein thrombosis
- coronary artery bypass after three months acceptable, preferable six months
- angiogram/interventions after two weeks
- hypertension > 180/110 mm Hg, hypotension < 80/50 mm Hg
- uncontrolled atrial fibrillation
- peripheral vascular disease
- left ventricular hypertrophy

- severe pulmonary disease
- bleeding diathesis (coumadin therapy with PT/INR > 3.0)
- sustained arrhythmias
- arrhythmias that interfere with machine triggering
- active thrombophlebitis
- severe extremity vaso-occlusive disease
- pregnancy
- severe congestive heart failure
- burn, wound or fracture of any limb subject to treatment

Much of the published literature has evaluated ECP for cardiac-related conditions such as angina pectoris and congestive heart failure (CHF). ECP has also been proposed as treatment for several other conditions (e.g., restless leg syndrome, sudden deafness, stroke, erectile dysfunction, hepatorenal syndrome, retinal artery occlusion) (Manchanda, et al., 2007).

According to the Centers for Disease Control and Prevention (CDC) (2022), about 697,000 people (i.e., one in five deaths) in the United States died from heart disease in 2020. For men, women, and people of most racial and ethnic groups, it is the leading cause of death. In 2017 and 2018, heart disease cost the United States about $229 billion each year for health care services, medicines, and lost productivity due to death. Coronary heart disease is the most common type of heart disease affecting about 7.2% (i.e., 20.1 million) of adults in the United States. In a 2019 health spotlight on racial and ethnic disparities in heart disease, the CDC stated that “non-Hispanic Black persons were more than twice as likely as non-Hispanic Asian or Pacific Islander persons to die of heart disease between 1999 and 2017”. The prevalence rate for non-Hispanic white adults in 2017 was 11.5%, 9.5% for non-Hispanic Black adults, 7.4% for Hispanic adults, and 6.0% for non-Hispanic Asian adults. Non-Hispanic Black adults were more likely to have the risk factors of hypertension (n=42.1%) and obesity (n=47.5%) compared to Hispanics (n=29.4% and n=46.9% respectively), non-Hispanic white (n=28.7% and n=38.2% respectively), and non-Hispanic Asian (n=27.2% and 12.4% respectively). Hispanic and non-Hispanic Black adults were most likely to have diabetes (n=21.5% and 19.6% respectively) compared to non-Hispanic white (n=13.0%) and non-Hispanic Asian (n=14.5%). Non-Hispanic whites (n=12.6%), Hispanics (n=11.2%), non-Hispanic Asians (n=10.7%), and non-Hispanic Blacks (n=10.2%) were equally as likely to have high total cholesterol.

U.S. Food and Drug Administration (FDA)
The FDA granted 510(k) approval for the CardiAssist™ External Counterpulsation (ECP) System in 1980. Since then, additional ECP devices, including but not limited to: Soulaire External Counterpulsation System, Enhanced External Counterpulsation Device Plus Omay-A, and Pure Flow External Counterpulsation Device have received 510(k) approval for use in treating stable and unstable angina pectoris, acute MI, cardiogenic shock, and CHF (FDA, 2020a; FDAb, 2020b; FDA, 2018; FDA, 2016).

Chronic Stable Angina Pectoris
Chronic, intractable or refractory, stable angina pectoris, also known as end-stage coronary artery disease (CAD), is defined as “a chronic condition characterized by the presence of angina caused by coronary insufficiency in the presence of CAD which cannot be controlled by a combination of medical therapy, angioplasty and coronary bypass surgery. The presence of reversible myocardial ischemia should be clinically established to be the cause of the symptoms. Chronic is defined as a duration of more than three months” (Mannheimer, et al., 2002). Myocardial ischemia relates to the insufficient supply of oxygenated blood to the myocardium due to atherosclerosis, coronary artery spasm, thrombosis, and a variety of other medical conditions. Of the symptoms related to poor circulation of blood (e.g., dizziness and shortness of breath) the cardinal symptom is angina. Angina is characterized by severe chest pain with radiation of pain to the jaw or left arm (Deer and Raso, 2006; Mannheimer, et al., 2002; Eliasson, et al., 1996).

Anginal pain is most often treated with medication (e.g., calcium-channel blockers, nitrates, and Beta (ß)-blocking agents), revascularization surgery (i.e., coronary artery bypass grafting [CABG] and percutaneous transluminal coronary angioplasty [PTCA]) or non-surgical revascularization (e.g., balloon angioplasty, intracoronary stenting, rotational atherectomy). Despite medical and surgical treatment, there is a subset of

patients with CAD who do not respond to conventional medical therapy, are not candidates for revascularization procedures, or who have had previous revascularization surgery and in whom anginal pain persists. Few options exist for patients with chronic stable anginal pain resistant to conventional treatment. Therapies aimed at those patients with chronic stable angina pectoris refractory to conventional treatment include: transmyocardial laser revascularization (TMR), thoracic epidural anesthesia, external counterpulsation (ECP), transcutaneous electrical nerve stimulation (TENS), and spinal cord stimulation (SCS). There is limited evidence directly comparing these multiple therapeutic methods in the peer-reviewed medical literature (Bondesson, et al., 2008; Eliasson, et al., 1996).

To assist physicians in grading the severity of angina pectoris, the New York Heart Association (NYHA) and the Canadian Cardiovascular Society (CCS) published functional classifications based upon clinical severity and prognosis for patients with cardiac disease. The classifications relate symptoms to everyday activities and quality of life (QOL). The scientific studies for ECP have typically included those patients who are categorized as CCS class III or class IV. CCS is a modification of the NYHA functional classification that allows patients to be categorized in more specific terms (Appendix A) (Heart Failure Society of America [HFSA], 2020; Gibbons, et al., 2003; American Heart Association [AHA], 1994, 2011; CCS, 1976).

Literature Review: Although the evidence supporting the use of external counterpulsation (ECP) comes from a number of uncontrolled studies and case series reports, analyses of patient registry data and limited controlled studies, a course of ECP has become the standard of care for a subset of individuals with chronic stable angina as defined by the Canadian Cardiovascular Society (CCS) Functional Classification III or IV or equivalent in patients who have failure, contraindication or intolerance to pharmacological management and are not considered candidates for angioplasty or revascularization or in patients with severe chronic stable angina who have undergone angioplasty or revascularization and continue to be symptomatic (Rayegani, et al., 2021; Shah, et al., 2010; Braith, et al., 2010; Bondesson, et al., 2008; Campbell, et al., 2008; Erdling, et al., 2008; Loh, et al., 2008; Lawson, et al., 2006; Loh, et al., 2006; Pettersson, et al., 2006; Ochao, et al., 2006; Nichols, et al., 2006; Michaels, et al., 2004; Holubkov, et al., 2002; Michaels, et al., 2002; Barsness, et al., 2001; Arora, et al., 1999; Lawson, et al., 2000a, 1998, 1996a, 1996b, 1995).

Professional Societies/Organizations: The 2014 American College of Cardiology/American Heart Association/American Association for Thoracic Surgery/Preventive Cardiovascular Nurses Association/Society for Cardiovascular Angiography and Interventions/Society of Thoracic Surgeons focused update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease (SIHD) recommends enhanced external counterpulsation (EECP) for relief of refractory angina in patients with SIHD (Class IIb Level of Evidence B). This recommendation has not changed from the 2012 recommendation. A class IIb, level of evidence B recommendation indicates the procedure/treatment may be considered. The benefit is equal to or greater than the risk. Additional studies with broad objectives are needed, and additional registry data would be helpful. The usefulness/efficacy is less well established, and greater conflicting evidence from single randomized trials or nonrandomized studies exists (Fihn, et al., 2014).

The ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) 2011 update to the 2005 practice guideline for percutaneous coronary intervention does not mention ECP. The 2015 focused update of the 2011 guideline does not mention external counterpulsation (ECP) (Levine, et al, 2015; 2011).

The American College of Physicians clinical practice guideline for the primary care management of chronic stable angina and asymptomatic suspected or known CAD states under the category of alternative therapies for patient with refractory angina that evidence is lacking for the use of ECP. ECP should be used only in patients who cannot be managed adequately by medical therapy and who are not candidates for interventional or surgical revascularization (Snow, et al., 2004).

The ACC/AHA 2002 guideline update for the management of patients with chronic stable angina assigns a level of evidence of Class IIb (the usefulness/efficacy is less well established by evidence/opinion). This suggests there may be some benefit, but additional clinical trial data is needed before ECP can be recommended definitively (Gibbons, et al., 2003). ECP was not mentioned in the 2007 focused update of the ACC/AHA 2002 guidelines for the management of patients with chronic stable angina (Fraker, et al., 2007).

Literature Review

Heart Failure: Zhou et al. (2021) conducted a meta-analysis of eight randomized controlled trials (RCT) to evaluate the safety and efficacy of enhanced external counterpulsation (EECP) on exercise capacity and quality of life in patients with chronic heart failure (CHF). A total of 823 participants with a mean age of 64.6 years were enrolled. Individual RCT sample sizes ranged from 40–180. Limitations were not placed on race population, religion, or gender. RCTs evaluating EECP were included if patients were diagnosed with CHF with reduced, mid-range, or preserved ejection fraction. The intervention group (n=409) received EECP for a total of either 36 hours (1 hour/day, 6 days per week, 6 weeks) or 35 hours (1 hour/day, 7 days per week, 7 weeks). The comparators (n=414) were: diet, routine nursing care, pharmacologic therapy, or sham EECP. The primary outcome measures were exercise capacity (e.g., peak VO2, VO2 maximum, exercise time, walking distance (six minute walking distance), and endurance exercise) and quality of life (QOL) (e.g., Minnesota Living with Heart Failure Questionnaire (MLHFQ) and SF-36). Secondary outcome measures included: B-type natriuretic peptide, N-terminal pro-brain natriuretic peptide (NT-pro-BNP), left ventricular ejection fraction (LVEF), and serious adverse events (SAES). Follow-up ranged from five weeks to six months. Six studies evaluated the six minute walking distance test and found significantly improved results ($p<0.00001$). Two studies evaluated QOL using the MLHFQ and did not find a significant improvement ($p=0.07$). LVEF was reported in four studies and was found to be significantly improved in the EECP group compared to the control group ($p=0.0004$). Five studies evaluated NT-pro-BNP and results showed significantly reduced levels in the EECP group compared to the control group ($p<0.00001$). Two studies reported on SAES and found three events including: one patient with worsening heart failure, one with pulmonary embolism, and one with deep vein thrombosis. Author noted limitations included: difficulty with treatment allocation, heterogeneity of heart failure etiology and classification, small sample sizes, and short-term follow-up. Additional high-quality studies with larger sample sizes and longer-term follow-up are needed to assess the safety and efficacy of EECP use on patients with chronic heart failure.

In a randomized controlled trial, Feldman et al. (2005, 2006) examined the effects of external counterpulsation (ECP) in the treatment of CHF. The Prospective Evaluation of Enhanced External Counterpulsation in Congestive Heart Failure (PEECH) study randomized 187 patients with mild or moderate heart failure to receive either 35 one hour sessions of ECP treatment in addition to optimal pharmacotherapy, or pharmacotherapy alone. Prior to randomization, medical therapy was optimized for all individuals. Only individuals with stable heart failure (secondary to ischemic heart disease or idiopathic-dilated cardiomyopathy), with LVEF < 35 and NYHA class I or II were eligible for inclusion. The study evaluated changes in: exercise duration (percentage of individuals with increase ≥60 seconds on treadmill, absolute change [seconds]); peak volume of oxygen uptake (Vo2) (percentage of individuals with increase ≥1.25 ml/min/kg); quality of life measures (SF-36 and Minnesota Living with Heart Failure Questionnaire) and New York Heart Association (NYHA) functional classification status. Although the study reports improved exercise tolerance and NYHA functional classification in ECP-treated individuals, several study design flaws undermine the reliability of the study findings. The patients undergoing ECP could not be blinded, increasing the likelihood of the placebo effect. Fewer patients completed the study in the active treatment group (76%) than in the control group (86%), largely due to more patients in the ECP group discontinuing due to an adverse experience (11.8% ECP versus 3.2% control), suggesting that there may be a difference that affects the outcome). Adverse events that occurred in relation to the application of ECP therapy resulting in discontinuation included sciatica (one patient), leg pain (one patient), and arrhythmia, which interfered with application of the therapy (two patients). One other ECP subject suffered a non–Q-wave myocardial infarction during the treatment period not attributable to the therapy. During the follow-up period, six additional subjects from the ECP group discontinued due to worsening heart failure. Adverse events in the control group leading to discontinuance included two deaths during the treatment period and one instance of atrioventricular block during the follow-up period. The short follow-up period (six months) limits conclusions regarding the durability of treatment effects. Exclusion of NYHA functional class III and IV, limit the ability to apply the study findings to the general population of patients with heart failure who are seen in clinical practice. Methodological flaws associated with this study precludes the ability to generalize findings and draw strong conclusions regarding the impact on health outcomes.

In a noncontrolled study, Soran et al. (2006) used International EECP Patient Registry data to evaluate the two-year outcomes of patients (n=363) who had severe LV dysfunction treated with ECP for angina pectoris. Immediately post-ECP therapy, 77% of the patients improved more than one angina class, and 18% had no angina. At two years, 73% (n=265) of the patients completed follow-up, and 55% had sustained improvement in

angina class. At baseline, 58% improved quality of life compared to 63% at two-year follow-up. This study had no control group to assess outcomes.

In a prospective cohort study, Lawson et al. (2005) studied the immediate and one-year benefit from ECP in angina patients with diastolic versus systolic heart failure (n=746). Regardless of the degree of left ventricular dysfunction, ECP benefited anginal symptoms in heart failure patients. However, more rigorous evaluation of the impact of ECP on clinical outcomes will require a randomized trial.

Lawson et al. (2001) analyzed ECP results of 1957 patients, 548 (28%) of whom had histories of CHF at baseline; all 1957 patients were reassessed at six months. Immediately after ECP, 68% of the CHF cohort demonstrated a CCS class improvement of one or more levels, and 0.9% demonstrated a worsening in functional class. The improvement was maintained over the six-month period. In addition, 58% felt their overall health had improved, and 55% felt their quality of life had improved. The mean improvement in CCS functional angina class was less in the CHF cohort than in the non-CHF cohort, and the CHF cohort was significantly more likely to discontinue treatment, generally due to exacerbation of CHF symptoms.

Professional Societies/Organizations: The 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) Guideline for the Management of Heart Failure and the 2017 Focused Update to the 2013 guideline does not mention external counterpulsation therapy (Yancy, et al., 2013; 2017).

ECP for Other Indications
The safety, effectiveness and long-term outcomes of ECP for conditions other than chronic stable angina pectoris has not been established in the peer-reviewed medical literature (this list may not be all inclusive) (Sathyamoorthy, et al., 2022; Dayrit, et al., 2021; Raeissadat, et al., 2018; Tecson, et al., 2016; Beck, et al., 2015; Zhang, et al., 2015; Rampengan, et al., 2015; Agrawal, et al., 2014; Lin, et al., 2012; Xin, et al., 2010; Thakkur, et al., 2010; Alexandrov, et al., 2008; Manchanda, et al., 2007; Lawson, et al., 2007; Soran, et al., 2006; Lawson, et al,. 2005; Werner, et al., 2005; Werner, et al., 2004; Lawson, et al., 2001; Taguschi, et al., 2000):

- arrhythmia
- aortic insufficiency
- congestive heart failure
- erectile dysfunction
- fatigue/malaise
- hepatorenal syndrome
- long COVID syndrome (Post COVID)
- microvascular angina (cardiac syndrome X)
- peripheral vascular disease or phlebitis
- restless leg syndrome
- retinal artery occlusion
- severe hypertension (>180/100 mm Hg)
- stroke
- sudden deafness and tinnitus
- unstable angina
- vertebrobasilar insufficiency

Use Outside of the US
ECP devices are available in several countries other than the United States; device availability, regulatory guidance, and criteria for coverage vary according to the available health service options for each country.

Appendix A

New York Heart Association and Canadian Cardiovascular Society Functional Classifications Class	New York Heart Association Functional Classification	Canadian Cardiovascular Society Functional Classification
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous or rapid or prolonged exertion at work or recreation.
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.
(Heart Failure Society of America [HFSA], 2020; Gibbons, et al., 2003; American Heart Association [AHA], 2017; Canadian Cardiovascular Society [CCS], 1976).		

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	External COUNTERPULSATION (ECP) Therapy for Severe Angina (20.20)	3/20/2006
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
G0166	External counterpulsation, per treatment session

***Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.**

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