Clinical Policy Bulletin:
External Counterpulsation (ECP)

Number: 0262

Policy

I. Aetna considers a course of up to 35 sessions of external counterpulsation (ECP) medically necessary for members who meet both of the following criteria:

A. Members with disabling chronic stable angina (New York Heart Association Class III or Class IV angina) (see Appendix);

and

B. Members are refractory to maximum medical therapy and not readily amenable to surgical intervention such as percutaneous transluminal coronary angioplasty (PTCA) or cardiac bypass due to any of the following:

Their condition is inoperable; or
They are at high-risk of operative complications or post-operative failure; or
Their coronary anatomy is not readily amenable to such procedures; or
They have co-morbid states that create excessive risk.

There is no proven benefit to extending a course of ECP beyond 35 sessions.

II. Aetna considers repeat courses of ECP medically necessary for persons with chronic stable angina if all of the following criteria are met:

A. Member meets medical necessity criteria for ECP in section I above; and

B. Prior ECP has resulted in a sustained improvement in symptoms, with:

1. A significant (greater than 25 %) reduction in frequency of anginal symptoms; or
2. Improvement by 1 or more anginal classes; and

C. Three or more months has elapsed from the prior ECP treatment.

III. Aetna considers the use of ECP for all other conditions (e.g., abnormal glucose tolerance, aortic insufficiency, arrhythmia, erectile dysfunction, fatigue/malaise, heart failure, hepato-renal syndrome, hypertension, peripheral vascular disease or phlebitis, restless leg syndrome, retinal artery occlusion, rotational vertebro-basilar insufficiency, stroke, sudden deafness, tinnitus, and unstable angina) experimental and investigational because its effectiveness for indications other than the one listed above has not been established.

IV. Aetna considers hydraulic versions of these devices not medically necessary.

Background

External counterpulsation (ECP) is a non-invasive, outpatient treatment for coronary artery disease with angina refractory to medical and/or surgical therapy. A series of 3 compressive air cuffs that inflate and
deflate in synchronization with the patient's cardiac cycle via microprocessor-interpreted ECG signals are wrapped around each leg; one at calf level, another slightly above the knee and the third on the thigh. The cuffs are larger versions of the familiar blood pressure cuff. During diastole the 3 sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole, which produces a rapid drop in vascular impedance, a decrease in ventricular work-load and an increase in cardiac output.

In the short-term, this method of therapy is thought to deliver more oxygen to the ischemic myocardium by increasing coronary blood flow during diastole, while at the same time reducing the demand for oxygen by diminishing the work requirements of the heart. Long-term benefit is expected to result as coronary collateral flow to ischemic regions of the myocardium is increased. A full course of ECP typically involves 5 hours of treatment per week, delivered in 1- to 2-hour sessions for 7 weeks, for a total of 35 hours of treatment (Arora et al, 1999; CMS, 2006). The pivotal randomized controlled trial of ECP, the MUST-ECP trial, employed a 35-hour protocol (Arora et al, 1999). There is no reliable evidence that clinical outcomes of ECP are improved with prolonged courses of treatment. Michaels et al (2005) reviewed registry data to assess the frequency, efficacy, predictors, and long-term success of repeat ECP therapy in relieving angina in patients who had chronic angina and had undergone a full course of ECP. Within 2 years of the initial course of ECP, the rate of repeat ECP was 18 %, which occurred at a mean interval of 378 days after initial ECP. Of those who underwent repeat ECP, 70 % had a decrease of 1 or more angina classes at the end of repeat ECP with similar decreases in nitroglycerin use. Although patients who underwent repeat ECP did benefit from the 2 courses of therapy, the symptomatic improvement was not sustained. 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).

Clinical trials have demonstrated that the beneficial effects of ECP, including increased time until onset of ischemia and a reduction in the number and severity of anginal episodes. These effects are not only sustained between treatments, but may persist for several months to 2 years after completion of a course of therapy.

While the Food and Drug Administration has granted Enhanced External Counterpulsation (EECP) 510(k) clearance for treating a variety of conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the effectiveness of EECP for conditions other than stable disabling angina (e.g., heart failure and retinal artery occlusion) has not been established in the peer-reviewed medical literature.

Manchanda and Soran (2007) stated that numerous clinical trials in the last 2 decades have shown EECP therapy to be safe and effective for patients with refractory angina with a clinical response rate averaging 70 % to 80 %, which is sustained up to 5 years. It is not only safe in patients with co-existing heart failure, but also is shown to improve quality of life and exercise capacity and to improve left ventricular function long-term. Interestingly, EECP therapy has been studied for various potential uses other than heart disease, such as restless leg syndrome, sudden deafness, hepatorenal syndrome, and erectile dysfunction. Moreover, Arora and Shah (2007) stated that EECP has been proven to provide symptomatic benefit in angina patients, but has not been proven to show an increase in life expectancy or decrease in cardiovascular events. Furthermore, EECP in heart failure has been proven to be safe, but its effectiveness is still uncertain.

Alexandrov et al (2008) determined ECPs effect on middle cerebral artery (MCA) blood flow augmentation in normal controls as a first step to support future clinical trials in acute stroke. Bilateral 2-MHz pulsed wave transcranial Doppler (TCD) probes were mounted by head frame, and baseline M1 MCA TCD measurements were obtained. External counterpulsation was then initiated using standard procedures for 30 mins, and TCD readings were repeated at 5 and 20 mins. Physiological correlates associated with ECP-TCD waveform morphology were identified, and measurable criteria for TCD assessment of ECP arterial mean flow velocity (MFV) augmentation were constructed. A total of 5 subjects were enrolled in the study. Pre-procedural M1 MCA TCD measurements were within normal limits. Onset of ECP produced an immediate change in TCD waveform configuration with the appearance of a second upstroke at the diastolic notch, labeled peak diastolic augmented velocity (PDAV). Although end-diastolic velocities did not increase, both R-MCA and L-MCA PDAVs were significantly higher than baseline end-diastolic values (p < 0.05 Wilcoxon rank-sum test) at 5 and 20 mins. Augmented MFVs (aMFVs) were also significantly higher than baseline MFV in the R-MCA and L-MCA at both 5 and 20 mins (p < 0.05). The authors concluded that ECP induces marked changes in cerebral arterial waveforms and augmented peak diastolic and mean MCA flow.
velocities on TCD in 5 healthy subjects. In this regard, Han and Wong (2008) stated that randomized, controlled trials with a large sample size are needed to further define the safety and effectiveness of ECP in acute stroke management.

A Cochrane systematic evidence review concluded that there is a lack of reliable and conclusive evidence that EECP can improve symptoms of angina in patients with chronic stable or refractory forms of the condition (Amin et al, 2010). The authors identified 1 trial, with 139 participants, that met criteria for inclusion in the review. The authors found that poor methodological quality, in terms of trial design and conduct, incompleteness in reporting of the review's primary outcome, limited follow-up for the secondary outcomes and subsequent flawed statistical analysis, compromised the reliability of the reported data. The authors explained that this trial failed to address the characteristics of interest satisfactorily, in terms of severity of angina, for the participants in this review. Participants with the most severe symptoms of angina were excluded; therefore the results of this study represent only a subsection of the broader population with the disorder, are not generalizable and provide inconclusive evidence for the effectiveness of EECP therapy for chronic angina pectoris.

Similarly, an assessment by the National Institute for Health Research Health Technology Assessment Programme found that although EECP is cost-effective if the observed quality of life benefits are assumed to continue throughout a patient's lifetime, there is insufficient evidence for its long-term clinical effectiveness in refractory stable angina (McKenna et al, 2009).

Vertebro-basilar insufficiency (VBI) is a condition in which decreased blood volume of the vertebral artery and basilar artery results in insufficient blood supply to certain parts of the brain. This will lead to a variety of syndromes (e.g. difficulty in talking, disequilibrium/dizziness/vertigo, gait disturbances, headache, impaired vision, position-related nystagmus, and weakness or numbness on one or both sides of the body). Xin et al (2010) examined the effectiveness of EECP and traction therapy for patients with rotational VBI. A total of 163 patients with clinically suspected rotational VBI caused by cervical spondylosis were enrolled in this study. They were randomly assigned into 3 groups: (i) EECP + traction, (ii) EECP, and (iii) traction. All patients and 50 healthy volunteers received transcranial color Doppler examination of the vertebral artery and basilar artery in both a neutral cervical spine position and a rotational position. Within 3 days after treatment, 47 (84 %) patients in EECP + traction group, 32 (61 %) patients in EECP group, and 8 (15 %) patients in traction group achieved successful outcomes, while at 3 months' follow-up, 45 (80 %) patients in EECP + traction group, 34 (64 %) in EECP group, and 3 (6 %) in traction group achieved successful outcomes. With head rotation, the percentage of reduction of blood flow velocities of the vertebro-basilar artery (VBA) in patients was much greater than that of the healthy volunteers (p < 0.01). After treatment, rotational blood flow velocity reduction percentage of VBA in each treatment group was much lower than that of each group before treatment. Patients in the EECP + traction group experienced the greater decrease of rotational blood flow velocity reduction percentage of VBA than patients in the EECP group. The authors concluded that EECP and traction therapy can relieve the symptoms of rotational VBI, improve the rotational reduction of vertebro-basilar blood flow, and reduce the increased arterial impedance. Moreover, they stated that further long-term investigations are needed to confirm these findings.

In a Cochrane review, Lin et al (2012) evaluated the safety and effectiveness of ECP for acute ischemic stroke. These investigators searched the Cochrane Stroke Group Trials Register (June 2011), Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, 2011 Issue 2), MEDLINE (1948 to June 2011), EMBASE (1980 to June 2011), CINAHL (1982 to June 2011), AMED (Allied and Complementary Medicine) (1985 to June 2011), China Biological Medicine Database (CBM) (1978 to June 2011), Chinese National Knowledge Infrastructure (CNKI) (1979 to June 2011), Chinese Science and Technique Journals Database (VIP) (1989 to June 2011) and Wanfang Data (1984 to June 2011). They also searched ongoing trials registers, reference lists and relevant conference proceedings and contacted authors and manufacturers of ECP devices. Randomized controlled trials (RCTs) in which ECP (started within 7 days of stroke onset) was compared with sham treatment or no treatment, or ECP plus routine treatment was compared with routine treatment alone, in patients with acute ischemic stroke. Two review authors independently assessed trial quality and extracted data, checked for adverse events data and contacted trialists for missing information. These researchers included 2 trials involving 160 patients. Numbers of death or dependent patients at the end of at least 3 months follow-up were not reported in either of the included trials. The outcome measure used in the included trials was only the number of participants with improvement of neurological impairment after treatment according to the Modified Edinburgh-Scandinavian Stroke Scale (MESSS) or self-making criteria. External counterpulsation was associated with a significant increase in the number of participants whose neurological impairment improved (risk ratio (RR) 1.75, 95 % confidence interval (CI): 1.37 to 2.23). Only 1 trial reported no adverse events. The authors...
concluded that the methodological quality of the included studies was poor, and reliable conclusions could not be drawn from the present data. They stated that high-quality and large-scale RCTs are needed.

May (2013) stated that enhanced ECP (EECP) is a non-invasive therapy offered to patients with angina pectoris who have unacceptable chest pain despite medical treatment and who have no operative options. During EECP, 3 sets of pneumatic cuffs wrapped around the lower extremities are inflated to a pressure of 260 to 300 mm Hg in diastole. This creates an augmented diastolic blood pressure and an increase in coronary blood flow. The therapy is usually given for 1 hour 5 days a week in 7 weeks. The author concluded that EECP is known to reduce the frequency of angina, increase the quality of life and reduce the frequency of hospitalization.

An UpToDate review on “Possibly effective emerging therapies for heart failure” (Colucci, 2015) states that “Trials and registries of EECP included some patients with HF, some of whom had improvements in their exercise capacity following EECP therapy. The PEECH trial directly evaluated the possible benefit of EECP in patients with mild-to-moderate HF. One hundred and eighty-seven patients were randomly assigned standard medical therapy with seven to eight weeks of EECP or standard medical therapy alone. Patients assigned to EECP were slightly more likely to increase their total exercise time by more than 60 seconds (35 versus 25 percent with standard medical therapy). However, EECP did not have any effect on peak VO2. Thus, this study did not achieve positive results for its two primary endpoints. In addition, the results of this single-blind trial are subject to placebo effect. Further research will be necessary to define the impact of EECP in the treatment of HF”.

Martin et al (2014) stated that EECP improves resistance artery function in coronary artery disease patients. However, whether EECP elicits similar effects in persons with abnormal glucose tolerance (AGT) is unknown. These researchers provided novel evidence that EECP significantly improves resistance arterial function in the forearm of persons with AGT, whereas the calf only approached significance (p ≤ 0.10). These improvements were coincident with greater glycemic control, providing further insight into the potential mechanisms of EECP-mediated alterations in glycemia. These preliminary findings need to be validated by well-designed studies.

Appendix

New York Heart Association Functional Classification of Cardiac Disability:

Class I: Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.

Class II: Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.

Class III: Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.

Class IV: Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Source: Adapted from Goldman et al (1981).

CPT Codes / HCPCS Codes / ICD-9 Codes

Other CPT codes related to the CPB:

93922 Limited bilateral non-invasive physiologic studies of upper or lower extremity arteries, (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with transcutaneous oxygen tension measurements at 1-2 levels)
93923  Complete bilateral non-invasive physiologic studies of upper or lower extremity arteries, 3 or more levels (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional Doppler waveform recording and analysis at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension measurements at 3 or more level(s), or single level study with provocative functional maneuvers (eg, measurements with postural provocative tests or measurements with reactive hyperemia) 

**HCPCS codes covered if selection criteria are met:**

G0166  External counterpulsation, per treatment session

**ICD-9 codes covered if selection criteria are met:**

413.0 - 413.9  Angina pectoris [disabling, refractory to maximum medical therapy and not readily amenable to surgical intervention]

**ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):**

325  Phlebitis and thrombophlebitis of intracranial venous sinuses

333.94  Restless legs syndrome (RLS)

362.30 - 362.37  Retinal vascular occlusion

388.2  Sudden hearing loss, unspecified

388.30 - 388.32  Tinnitus

395.1  Rheumatic aortic insufficiency

401.0 - 401.9  Essential hypertension

411.1  Intermediate coronary syndrome [unstable angina]

424.1  Aortic valve disorders [aortic insufficiency]

427.0 - 427.9  Cardiac dysrhythmias

430-438.9  Cerebrovascular disease [stroke] [rotational vertebro-basilar insufficiency]

443.0 - 443.9  Other peripheral vascular disease

451.0 - 451.9  Phlebitis and thrombophlebitis

453.1  Thrombophlebitis migrans

454.1  Varicose veins of lower extremities with inflammation

572.4  Hepatorenal syndrome

593.81  Vascular disorders of kidney [renal artery occlusion]

607.84  Impotence of organic origin [erectile dysfunction]

780.71 - 780.79  Malaise and fatigue
The above policy is based on the following references:


46. Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat (MAS). Enhanced external counterpulsation (EECP). Health Technology Policy Assessment Update. Toronto, ON: MAS; March 2006. Available at:


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