HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Enhanced External Counter Pulsation (EECP)

Policy MP-010

Origination Date: 12/13/2023

Reviewed/Revised Date: 01/22/2025

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Current Effective Date: 01/22/2025

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Enhanced external counter pulsation is a noninvasive treatment (EECP) involving sequential pneumatic compression of the legs and buttocks coordinated with cardiac contractions. EECP is designed to increase diastolic aortic blood pressure, improve venous blood return, and decrease afterload on the left ventricle. The goal of EECP is to increase perfusion during diastole in patients with chronic angina pectoris, relieving pain and reducing impairment. EECP has been studied primarily as a treatment for patients with refractory angina and heart failure, as well as for other indications such as erectile dysfunction, ischemic stroke, myocardial infarction, and cardiogenic shock.

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 an acute myocardial infarction. In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the coronary collateral development. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms (ECGs) to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans covers enhanced external counter pulsation (EECP) when specific medical necessity criteria are met.

Medically Necessity Criteria require the Member to Meet ALL of the following:

A. The member has been diagnosed with disabling angina (New York Heart Association or Canadian Cardiovascular Society Class III or IV*);

B. The member is refractory to maximum medical therapy;

C. The member is not readily amenable to surgical intervention such as percutaneous transluminal coronary angioplasty (PTCA) or cardiac bypass due to one or more of the following:

   i. The member's condition is inoperable
   ii. The member is at high risk of operative complications or postoperative failure
   iii. The member's coronary anatomy is not readily amenable to such procedures
   iv. The member has co-morbid conditions that create excessive risk

D. The request is for no more than 35 sessions of treatment;

E. The member does not have any of the following contraindications including but not limited to:

   i. Severe congestive heart failure with ejection fraction < 30%
   ii. Aortic insufficiency
   iii. Cardiac catheterization within 2 weeks
   iv. Arrhythmia

U of U Health Plans covers repeat courses of EECP medically necessary when ALL of the following criteria are met:

A. The member meets medical necessity criteria in the previous section above;

B. Prior EECP therapy has resulted in a sustained improvement in symptoms with one or more of the following:

   i. An ability to stop ranolazine AND a lowered dose of, or ability to stop other agents such as beta-blockers, calcium-channel blockers and nitrates.
   ii. Improvement by one or more NYHA angina classes.
   iii. A significant (greater than 25 percent) reduction in frequency of angina symptoms.

C. Three or more months has elapsed since the prior EECP treatment.

*New York Heart Association Functional Classification of Cardiac Disability		*Canadian Cardiovascular Society Functional Classification
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or 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.
Class II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.	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.
Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain.	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.
Class IV	Symptoms of heart failure at rest. Any physical activity causes further discomfort.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.

Source: American Heart Association, Classes of Heart Failure. 2023; Canadian Cardiovascular Society [CCS]. 1976.

Hydraulic versions of EECP devices are considered investigational and are not covered.

U of U Health Plans considers EECP experimental and investigational for all other conditions including but not limited to the following:

- Congestive heart failure
- Acute retinal artery occlusion
- Restless leg syndrome
- Sudden deafness
- Hepatorenal syndrome
- Erectile dysfunction
- Treatment of Class II angina
- Arrhythmia
- Aortic insufficiency
- Peripheral vascular disease or phlebitis
- Severe hypertension
- Acute myocardial infarction
- Ischemic stroke
- Cardiogenic shock

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

Raeissadat et al. (2018) reviewed the effectiveness of EECP in patients suffering from erectile dysfunction (ED). PubMed, Medline, Google Scholar, Trip database, Scopus, and Cochrane library databases were searched for articles with the following search terms: enhanced external counterpulsation and erectile dysfunction. No restrictions with respect to study setting, date of publication, and language were imposed. From an initial set of 208 records, 4 studies were selected after a final review. A total of 177 patients with a mean age of 59.98 years were included in these studies, with 20 to 35 hours/week of EECP treatment; 3 studies used the International Index of Erectile Function questionnaire and 1 applied a four-item questionnaire and a peak systolic flow measurement. All of these parameters were significantly improved after the EECP treatment. The authors concluded that to the best of their knowledge, this was the first study reviewing the clinical effectiveness of EECP in patients with ED. According to the articles reviewed in this study, an improvement in erectile function following EECP treatment courses has been observed in patients with and without coronary artery disease without any significant adverse effects. Moreover, these investigators stated that since the safety and effectiveness of EECP were observed in non-controlled studies, there is a need for well-designed randomized clinical trial studies with larger sample sizes and long-term follow-up periods to evaluate this new and non-invasive therapeutic option in patients suffering from ED by excluding the confounders.

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.

Joli et al. (2022) noted that fatigue is recognized as one of the most commonly presented long-term complaints in individuals previously infected with SARS-CoV-2. In a systematic review, these investigators described symptoms, etiology, possible risk factors related to post-COVID-19 fatigue and the therapeutic approaches used for the treatment of post-COVID-19 fatigue. For the systematic literature search the databases PubMed, Web of Science, Cochrane Library, and PsycInfo were employed. All studies that met the inclusion criteria were analyzed for demographics, clinical data and treatment. Included were studies that focused on an adult population (18 to 65 years of age); elderly patients and patients with chronic somatic diseases that could also cause fatigue were excluded. These researchers identified 2,851, screened 2,193 and finally included 20 studies with moderate-to-high methodological quality, encompassing 5,629 subjects. Potential risk factors for post-COVID-19 fatigue were old age, female sex, severe clinical status in the acute phase of infection, a high number of co-morbidities, and a pre-diagnosis of depression/anxiety. Finally, a possible autoimmune etiology was suspected. Several therapeutic options have been tested mostly in small and uncontrolled studies so far: a Chinese herbal formulation improved breathlessness and fatigue. Moreover, molecular hydrogen (H_2) inhalation had beneficial health effects in terms of improved physical (6MWD) and respiratory function in patients with post-COVID-19. Patients also noticed improvement in fatigue after undergoing hyperbaric oxygen therapy (HBOT) and EECP. Finally, muscle strength and physical function were improved after undergoing an 8-weeks bi-weekly physical therapy (PT) course including aerobic training, strengthening exercises, diaphragmatic breathing techniques, and mindfulness training. However, the authors stated that larger and controlled studies (e.g., examining the effect of physical and/or psychotherapy for patients with post-COVID-19 fatigue) 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.

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 ($p \leq 0.10$). 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.

Badtieva et al. (2019) examined the effectiveness of EECP in the treatment and rehabilitation of patients with stages I to IIB obliterating atherosclerosis of the lower extremities (OALE). A total of 68 patients aged 50 to 78 years with stages I to IIb OALE in the presence of clinical symptomatology of arterial insufficiency were examined and treated. According to the method of treatment, patients were divided into 2 groups: 32 people received a standard drug therapy (a control group), and 36 patients had an EECP therapy cycle during the standard therapy (a study group). The frequency of characteristic complaints, pain-free walking distance, peripheral hemodynamics, and the ankle-brachial index (ABI) were assessed. Post-treatment leg pain on walking persisted in 11 (30.6 %) and 25 (78.1 %) patients in the study group and in the control one, respectively. There were leg cramps in 9 (25.0 %) and 14 (43.8 %) people and cold feet in 5 (13.9 %) and 25 (78.1 %) patients, respectively ($p < 0.05$). In the study group, the considerable increase in pain-free walking distance as compared to baseline values averaged 250 ±

31.2 m ($p < 0.05$), while that in the control group was only 64.5 ± 25.1 m ($p > 0.05$). The post-treatment increase in the leg and foot rheographic indices averaged 23.9 and 23.2 %, respectively, in the study group and 11.9 and 12.3 %, respectively, in the control group. The increases in ABI in the anterior and posterior tibial arteries were 31.4 and 35.2 %, respectively, in the study group ($p < 0.05$), and 16.0 and 13.0 %, respectively, in the control group ($p > 0.05$). The authors concluded that the findings of this study suggested that the use of EECP in the combination therapy of patients with stages I to II b OALE was safe and effective. These preliminary findings need to be validated by well-designed studies.

Zhao et al. (2020) noted that EECP is popular in China for the treatment of coronary heart diseases, but it may be an effective treatment for other populations. In a pilot study, these researchers examined the effect of EECP on exercise endurance of healthy people and chronic obstructive pulmonary disease (COPD) patients and provided intervention measures to improve their physical condition. Patients were randomly divided into the EECP and non-EECP groups. According to their maximal oxygen uptake, the volunteers were also sub-grouped into the normal, low exercise endurance, and COPD subgroups. Differences in exercise endurance were evaluated between the EECP and non-EECP groups before and after treatment. Cardiopulmonary exercise testing included anaerobic threshold oxygen uptake (AT-VO2Kg), maximum oxygen uptake (Max-VO2Kg), anaerobic threshold pulse (AT-O2puls), anaerobic threshold metabolic equivalent (AT-Mets), and maximum metabolic equivalent (Max-Mets). A total of 72 volunteers were enrolled. The EECP and non-EECP groups were similar in terms of age, sex, body mass index (BMI), blood pressure, heart rate, breathing frequency, AT-VO2Kg, Max-VO2Kg, AT-O2puls, AT-Mets, and Max-Mets ($p > 0.05$) before treatment. EECP significantly improved AT-VO2Kg, Max-VO2Kg, AT-O2puls, AT-Mets, and Max-Mets compared with the non-EECP group ($p < 0.05$). When analyzed according to sub-groups, the AT-VO2Kg, Max-VO2Kg, AT-O2puls, AT-Mets, and Max-Mets of the normal, low exercise endurance, and COPD subgroups were all significantly in creased after EECP ($p < 0.05$). The authors concluded that EECP significantly improved the exercise endurance of normal adults, low endurance adults, and COPD patients. Moreover, these researchers stated that these findings need to be validated using a large-scale, multi-center clinical trial. The drawbacks of this trial included the small sample size ($n = 13$ in the EECP COPD-subgroup), and short-term follow-up. Furthermore, stratified randomization was not used.

Varanasi et al. (2021) stated that a growing number of patients diagnosed with coronavirus disease 2019 (COVID-19) have been reported to have postural orthostatic tachycardia syndrome (POTS) following the acute phase. A 57-year-old woman was diagnosed with COVID-19 in December 2020. As a result of her acute illness, she was hospitalized for COVID pneumonia and respiratory failure, followed by stays at an acute care facility and home rehabilitation center. After the acute phase, the patient was diagnosed with long-COVID-19-associated POTS with symptoms such as fatigue, "brain fog" and dyspnea. The patient was referred to an EECP treatment center and underwent 15, 1-hour sessions over 3 weeks. Upon completion of therapy, the patient reported improvements with "brain fog" and the ability to perform activities of daily living (ADL). Her Patient-Reported Outcome Measurement Information System (PROMIS) Fatigue score was reduced by 3 points, six-minute walk distance (6MWD) increased by 85 feet, and Duke Activity Status Index (DASI) improved by over 15 points. EECP therapy was chosen due to the overlap in underlying pathology driving POTS and the mechanisms of action of EECP. The authors concluded that this report was the 1st case of using EECP for the successful management of COVID-19-associated POTS and warrants further trials.

Dayrit et al. (2021) noted that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus responsible for the COVID-19 pandemic. As patients recover from COVID-19, some continue to report persisting symptoms weeks to months after acute infection. These effects have been referred to as post-acute sequelae of SARS-CoV-2 infection (PASC). These investigators reported the case of a 38-year-old

woman suffering from PASC symptoms following acute COVID-19 in October 2020. During her acute infection phase, she had a home recovery and reported her predominant symptoms as fatigue, headaches, body pain, and shortness of breath. After most of her symptoms were resolved, she continued to have periodic episodes of fatigue and headaches, along with random shortness of breath while at rest and during activities for months beyond the acute phase of the illness. She also noted the presence of "brain fog" as if lacking the same clarity that she had before her illness. These symptoms persisted for 3 months before the patient underwent EECP therapy in 1-hour sessions, three times per week. This therapy was chosen based on the mechanism of action of EECP benefiting patients with ischemic cardiovascular diseases. After one week, her "brain fog" had improved, with shortness of breath improving after 1.5 weeks. The patient reported returning to pre-COVID health and fitness following about 5 weeks of EECP treatment. The authors concluded that, to their knowledge, this was the 1st case of using EECP for post-COVID shortness of breath, fatigue, and "brain fog". These researchers stated that further investigation is needed to validate these findings.

In a retrospective analysis of a contemporary, consecutive patient cohort, Sathyamoorthy et al. (2022) examined the use of EECP as a possible therapy for long COVID. This trial was carried out in 7 out-patient treatment centers; subject received 15 to 35 EECP treatments. Main outcome measures included the change from baseline in Patient Reported Outcome Measurement Information System (PROMIS) Fatigue; Seattle Angina Questionnaire (SAQ); Duke Activity Status Index (DASI); 6MWD; Canadian Cardiovascular Society (CCS) Angina Grade; Rose Dyspnea Scale (RDS); and Patient Health Questionnaire (PHQ-9). Compared to baseline, the PROMIS Fatigue, SAQ, DASI, and 6MWD improved by 4.63 ± 3.42 ($p < 0.001$), 21.44 ± 16.54 ($p < 0.001$), 18.08 ± 13.82 ($p < 0.001$), and 200.00 ± 180.14 ($p = 0.002$), respectively. CCS and RDS improved in 63 % and 44 % of patients, respectively. All patients unable to work before EECP were able to return post-therapy. The authors concluded that EECP significantly improved validated fatigue and cardiovascular-related markers in patients with long COVID. These researchers stated that these findings suggested that EECP may be beneficial for the management of long COVID symptoms; these promising findings are hypothesis-generating and should be further examined in a broader clinical investigation.

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”.

An UpToDate review on “COVID-19: Evaluation and management of adults with persistent symptoms following acute illness ("Long COVID")” (Mikkelsen and Abramoff, 2022) did not mention EECP as a management/therapeutic option.

UpToDate also looked at new therapies for angina pectoris (Simmons et al., 2022) and found that the efficacy of EECP was evaluated in the MUST-EECP trial, which randomly assigned 139 outpatients with angina, documented coronary artery disease, and a positive exercise tolerance test to 35 hours of active EECP using a cuff pressure of 300 mmHg or inactive counterpulsation using a cuff pressure of 75 mmHg over a four- to seven-week period of time. The following results were seen: 1) Active EECP was well

tolerated without limiting side effects. 2) Exercise duration increased to a similar degree in both the active and inactive EECP groups; there was also no significant difference in nitroglycerin use. 3) Patients undergoing active EECP had a significant increase in time to ≥1 mm ST segment depression compared to baseline (379 versus 337 seconds), while there was no change in the inactive group. 4) More patients undergoing active EECP had a decrease in anginal episodes and fewer had an increase in angina compared to the inactive group. Similar findings have been noted in multicenter registries. In a series of 363 patients, 72 percent improved from severe to no or mild angina and 52 percent discontinued the use of nitroglycerin. At two years, the decrease in angina persisted in 55 percent of patients, survival was 83 percent, and major adverse cardiac event-free survival was 70 percent. Repeat EECP was required in 20 percent. The mechanism of these benefits is not clear, but is probably related, at least in part, to improvements in stress-induced myocardial perfusion, left ventricular diastolic filling, peripheral arterial flow-mediated dilation, and endothelial function.

Furthermore, the 2022 American College of Cardiology (ACC)'s Expert Consensus Decision Pathway on cardiovascular sequelae of COVID-19 in adults (Gluckman et al, 2022) did not mention the use of EECP as a management option.

The 2012 American College of Cardiology/American Heart Association (ACC/AHA) guidelines on the management of patients with stable ischemic heart disease indicate EECP "may be considered for relief of refractory angina." This recommendation is based on Class IIb, Level of Evidence: B, which indicates the efficacy of the intervention is not well established and further studies would be helpful.

The 2014 American College of Cardiology/American Heart Association (ACC/AHA) issued a Focused Update on the 2012 guideline on the diagnosis and management of patients with stable ischemic heart disease in which they specifically reviewed their recommendation on EECP. Based on their review, the recommendation on EECP remains unchanged from the 2012 guideline.

Medicare has published a national coverage decision on EECP that mandates coverage for the following indications: "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…."

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).

Applicable Coding

CPT Codes

92971	Cardioassist-method of circulatory assist; external [when specified as outpatient EECP]

HCPCS Codes

G0166 External counterpulsation, per treatment session

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