Anthem

Clinical UM Guideline

Subject: Enhanced External Counterpulsation in the Outpatient Setting
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Description

This document addresses the use of enhanced external counterpulsation (EECP) in the *outpatient* setting. EECP is used to treat disabling, chronic, stable angina in individuals refractive to optimal medical therapy and not readily amenable to surgical intervention.

Clinical Indications

Medically Necessary:

I. A single* course of enhanced external counterpulsation (EECP) is considered **medically necessary** for individuals when the criteria below are met:
   A. Disabling, chronic, stable angina, (defined as Class III or Class IV Canadian Cardiovascular Society Classification [see definition section] angina or equivalent); **and**
   B. Individuals refractive to optimal 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:
      1. Condition is inoperable; **or**
      2. High risk of operative complications or postoperative failure; **or**
      3. Coronary anatomy is not readily amenable to such procedures; **and**
   C. None of the following comorbid conditions or contraindications that would result in excessive risk are present, including but not limited to the following:
      1. Aortic insufficiency (regurgitation might prevent diastolic augmentation); **or**,
      2. Arrhythmias such as atrial fibrillation, atrial flutter, ventricular tachycardia, and frequent premature ventricular beats (might interfere with the device's triggering mechanism); **or**
      3. Uncontrolled bleeding diatheses; **or**
      4. Severe heart failure; **or**
      5. Deep vein thrombosis, varicosities, or stasis ulcers; **or**
      6. Peripheral vascular disease, phlebitis (increased risk of thromboembolus); **or**
      7. Severe hypertension (treatment could produce diastolic blood pressure above acceptable limits); **or**
      8. Stroke.

   Note: *A *single course* of treatment consists of a total of 35 hours of EECP; treatment is administered for one to two hours daily, 5 days a week, for approximately 3½ to 7 weeks.

II. A repeat course of EECP therapy is considered **medically necessary** in individuals who met the criteria in section **(I)** above, have chronic stable angina and who have objectively demonstrated a response to EECP. This would include those individuals who demonstrate **one** or **more** of the following:
   A. Early improvement in radionuclide stress perfusion imaging compared to a pre-EECP baseline; **or**
   B. Reduction in antianginal medication use; **or**
   C. Improvement in exercise tolerance.

Not Medically Necessary:

The use of EECP is considered **not medically necessary** when the criteria above are not met and for **all** other indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
92971	Cardioassist-method of circulatory assist; external [when specified as outpatient EECP]
HCPCS	
G0166	External counterpulsation, per treatment session
ICD-10 Diagnosis	
I20.0-I20.9	Angina pectoris
I25.110-I25.119	Atherosclerotic heart disease of native coronary artery with angina pectoris
I25.700-I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris
I25.710-I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris
I25.720-I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris
I25.730-I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris
I25.750-I25.759	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris
I25.760-I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris
I25.790-I25.799	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris

When services are Not Medically Necessary:

For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Discussion/General Information

Enhanced external counterpulsation (EECP) is a non-invasive outpatient treatment that uses a specialized pants-like device that incorporates three cuffs that contain air bladders in them. These pants are attached to an air compression system and electrocardiogram (ECG). The compressor works in conjunction with the ECG to trigger the compressor to inflate or deflate the air bladders in a sequential manner, coordinated with the diastolic (resting) phase of heart function. The sequential compression begins near the feet and progresses towards the torso in order to force blood out of the lower extremities and back into major blood vessels and the heart. This acts to increase blood pressure in the aorta during the diastole, increasing blood delivery to the coronary arteries and the heart muscle.

EECP is used to treat angina, a condition characterized by chest pain due to insufficient blood flow to the heart. Treatment with EECP is intended to provide symptomatic relief of angina, improve blood flow to blood-deprived areas of heart muscle, and to improve a person's level of physical activity. Additionally, EECP is believed to enhance the development of new blood vessels in the heart and increase flow through existing coronary blood vessels. A course of treatment typically includes 35 hours of EECP performed in 1- to 2-hour sessions at a time in the physician's office. EECP is not intended as a first-line therapy for angina, and is reserved for treating cases of angina which do not respond to medical and/or surgical therapy.

The use of EECP for the treatment of disabling, chronic, stable angina in people who are not suitable candidates for surgical intervention has been established in the medical evidence. Several large-scale prospective studies evaluating the efficacy of EECP in people with chronic stable angina demonstrate significant improvements in anginal symptoms, myocardial perfusion, and output (Arora, 2002; Arora, 1999; Lawson, 2000; Loh, 2008; Soran, 2006; Urano, 2001; Weisfogel, 2001). One randomized, sham-controlled trial demonstrated significant improvement after 12 months of treatment for people who underwent a single 35-hour course of EEPC. In this study treatment-group, subjects reported significant improvements compared to sham treated individuals in all nine quality of life scales included on the Medical Outcomes Study SF-36 health survey, including the activities of daily living, ability to work, bodily pain, and others (Arora, 2002). Loh and colleagues reported on the results of a large case series study with 1427 participants who underwent a single course of 35 one-hour EECP treatments (2008). The authors reported that immediately following the treatment series, the proportion of subjects dropping at least one class on the Canadian Cardiovascular angina Classification system (CCS) was 77.9% and that 38.0% had dropped by 2 CCS classes. Based on participant reports, 76% of subjects experienced at least a 50% reduction in the frequency of angina symptoms. These improvements were durable and were noted to continue through to the three-year follow-up visits. There was also a significant decrease in calcium channel blocker and long-acting nitrate use at all follow-up points.

Study exclusion criteria for use of EECP included contraindications to individuals with: severe aortic insufficiency, arrhythmia, bleeding diatheses, congestive heart failure, deep vein thrombosis, varicosities or stasis ulcers, peripheral vascular disease or phlebitis, pregnant women or women of childbearing potential who do not employ a reliable contraceptive, receiving warfarin (Coumadin) therapy, severe hypertension (greater than 180/110 mmHg, stroke and unstable angina.

EECP has also been studied for the treatment of congestive heart failure. In 2002, Soran and colleagues reported on a feasibility study of EECP, as a treatment for congestive heart failure in 26 subjects. In this uncontrolled study, the subjects were treated with 35 daily, one-hour sessions and followed for 6 months after completion of the course of therapy. The study suggests that the treatment was safe and well tolerated.

Results from the PEECH trial (Prospective Evaluation of EECP in Congestive Heart Failure) have been published (Feldman, 2006). The article discusses the 6-month outcomes of the PEECH trial which was a randomized controlled trial of 187 subjects with mild to moderate symptoms of heart failure. Participants were selected to receive either EECP and pharmacologic therapy or pharmacologic therapy alone. At 6 months, the study identified significant improvement in the EECP group compared to the control group in exercise time (also 35% increased exercise time by at least 60 seconds compared to 25% of controls), and NYHA functional class. No significant differences were identified in peak volume oxygen uptake (VO_2), respiratory exchange rate, or measurements on the Minnesota Living with Heart Failure or Borg scales. While the results of this study are promising, small numbers of participants (71 subjects completed the EECP regime), a high dropout rate in the experimental group due to adverse experiences (24% vs. 14% in the control group), lack of blinding which the authors acknowledge may have allowed for a placebo effect and lack of a sham treatment group, hinder the value of the study results. Finally, a subgroup analysis of the study data found that significant improvement in exercise time was seen only in the subjects with ischemic cardiomyopathy (approximately 40 seconds compared to controls), and not in those with non-ischemic cardiomyopathy.

In a separate report, Abbottsmith and colleagues report on a subgroup analysis of the PEECH trial (2006). Their report focused on PEECH participants greater than 64 years of age. The study results indicated that at 6 months, exercise responder rate and peak VO_2 were significantly improved compared to the control group. NYHA classification was significantly improved compared to controls at 3 months follow-up but not at 6 months and Minnesota Living with Heart Failure scores were not found to be significantly different. Again, while these results are promising, the same limitations of the larger PEECH trial affect these subgroup results. The authors warn that, as a subgroup analysis, their data should be interpreted with caution, but that it may be of benefit in identifying subgroups in which additional research should be targeted. Data from a larger, blinded randomized controlled trial are needed to validate the PEECH trial findings.

In August 2020, the FDA approved the Enhanced External Counterpulsation Device Plus Omay-A (Omay Med Technologies Co., Ltd. Nanshan District, Shenzhen, China) through the 510K approval process. The device is approved for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy without the option for revascularization, as well as for use in healthy individuals to provide improved vasodilation and increased blood flow, with the oversight of a healthcare professional.

In 2014, the American College of Cardiology (ACC)/American Heart Association (AHA) /American Association for Thoracic Surgery (AATS)/Preventive Cardiovascular Nurses Association (PCNA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Thoracic Surgeons (STS) focused update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease (SIHD) issued recommendations for EECP for relief of refractory angina in individuals with SIHD (Class IIb Level of Evidence B). 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, 2014)

The 2015 ACC/AHA/SCAI focused update to the 2011 practice guideline for percutaneous coronary intervention, does not address EECP procedure/treatment. (Levine, 2016)

In 2022, the ACC/AHA published the updated key data elements and definitions for chest pain and acute myocardial infarction: a report of the AHA/ACC Joint Committee of Clinical Data Standards. The document does not address the use of EECP treatment for

angina (Anderson, 2022).

The evidence regarding the use of EECP for other indications, including other anginal or cardiac conditions, such as non-disabling stable angina, unstable angina, CHF, stroke, or for use in healthy individuals to provide improved vasodilation and increased blood flow, is insufficient to allow conclusions to be made.

Definitions

Angina: A condition characterized by chest pain, due to insufficient blood flow to the heart.

Aortic Insufficiency: A condition caused by back flow of blood from the aorta into the left ventricle of the heart in between beats because of failure of an aortic valve to close properly.

Arrhythmia: A condition caused by an abnormal heartbeat; includes atrial fibrillation, atrial flutter, ventricular tachycardia, and frequent premature ventricular beats.

Bleeding diathesis: The occurrence of excessive bleeding.

Canadian Cardiovascular Society Score: This organization defines anginal classes as follows:

- Class I - Ordinary physical activity does not cause angina;
- Class II - Slight limitation of ordinary activity;
- Class III - Marked limitation of ordinary physical activity;
- Class IV – Inability to carry on physical activity without discomfort.

Cardiac Bypass: A surgical procedure that re-routes the blood flow supplying the heart to prevent heart attacks.

Cardiac Catheterization: A diagnostic procedure that involves passing a catheter (for example, a thin flexible tube) through an artery or a vein to the heart, and into a coronary artery; dye that can be seen on x-rays is then injected into the heart to produce angiograms (for example, x-ray images) of the coronary arteries and the left ventricle, the heart's main pumping chamber; it may also be used to measure pressures in the pulmonary artery and to monitor heart function, usually in critically ill individuals.

Comorbid States: Diseases that exist at the same time as other diseases within the same individual; for instance, if an individual has both diabetes and high blood pressure, they are considered comorbid conditions.

Congestive Heart Failure: A condition caused by a weakening of the heart muscle where the heart is unable to adequately pump blood to the body.

Deep Vein Thrombosis: A condition characterized by blood clots forming in the main veins of the legs when a vein is damaged or if the flow of blood slows down or stops; clots may become loosened and travel to the lungs causing a pulmonary embolus, a life-threatening condition.

Dyspnea: Shortness of breath.

Enhanced External Counterpulsation (EECP): A device that squeezes the leg, and in some circumstances the buttocks, to increase blood and fluid flow back to the heart.

Hypertension: High blood pressure.

Palpitation: An abnormally fast heartbeat.

Percutaneous Transluminal Coronary Angioplasty (PTCA): Also known as coronary artery balloon dilation or balloon angioplasty; a surgical procedure where a long thin surgical tool is passed through the blood vessels to the main arteries that supply blood to the heart; the tools are then used to widen the blood vessels to improve blood flow.

Peripheral Vascular Disease: A common circulation problem in which the arteries that carry blood to the legs or arms become narrowed or clogged causing cold hands and feet, nerve problems, and problems with healing.

Phlebitis: Inflammation of a vein resulting in decreased or obstructed blood flow through the vessel.

Stasis Ulcers: A condition characterized by the disintegration of skin due to the buildup of fluid in the tissues that do not have enough oxygen to support adequate tissue function.

Varicosities: Abnormally, markedly swollen or dilated veins, as occurs with poor circulation to the limbs.

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History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Discussion, References and Website sections.
Revised	11/10/2022	MPTAC review. Revised MN statement reformatting criteria and adding list of comorbid conditions and contraindications to EECP. Revised NMN statement removing list of contraindications. Updated Discussion, Coding and References sections.
Reviewed	11/11/2021	MPTAC review. Updated Discussion/General Information, References, and Websites sections.
Reviewed	11/05/2020	MPTAC review. Updated Discussion, References and Websites sections. Reformatted Coding section.
New	11/07/2019	MPTAC review. Initial document development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.