

Medical Benefit		Effective Date: 01/01/14	Next Review Date: 07/17
Preauthorization	Yes	Review Dates: 02/07, 11/07, 9/08, 03/09, 01/10, 01/11, 01/12, 01/13, 09/13, 07/14, 07/15, 07/16	

Preauthorization is required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Description

Enhanced external counterpulsation (EECP) is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. It 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 and ischemic stroke.

Summary of Evidence

The evidence on the efficacy of EECP for treatment of chronic angina is insufficient to form conclusions. There is only one blinded RCT that includes clinical outcomes, and this trial reported benefit on only one of four main angina outcomes. Additional small randomized controlled trials (RCTs) report changes in physiologic measures associated with EECP but do not provide relevant evidence on clinical efficacy. The evidence from observational studies, including registry studies with large numbers of patients, adds little to determinations of efficacy. This is because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect.

For the treatment of heart failure, the evidence is of a similar nature. There is one RCT that includes clinical outcomes, and this trial reports modest benefits on some outcomes, and no benefit on others. The observational studies on EECP in heart failure have the same limitations as do the studies on chronic angina. There is very limited evidence on the use of EECP for indications other than chronic angina or heart failure.

Policy

The use of EECP is **medically necessary** for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification), are refractory to maximum medical therapy, and who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty (PTCA) or cardiac bypass because:

1. Their condition is inoperable, or at high risk of operative complications or post-operative failure; or
2. Their coronary anatomy is not readily amenable to such procedures; or

3. They have co-morbid states, which create excessive risk.

EECP must be administered by a licensed physician. The Medical Director may authorize a second course of therapy after a medical review.

The use of EECP to treat all other cardiac conditions, including but not limited to congestive heart failure, acute myocardial infarction and cardiogenic shock are **investigational**. Other **investigational** uses include erectile dysfunction, or ischemic stroke.

Policy Guidelines

This Protocol only addresses the outpatient uses of EECP.

Background

EECP uses timed, sequential inflation of pressure cuffs on the calves, thighs, and buttocks to augment diastolic pressure, decrease left ventricular (LV) afterload, and increase venous return. Augmenting diastolic pressure displaces a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and the resistance in the coronary arteries is at a minimum. The resulting increase in coronary artery perfusion pressure may enhance coronary collateral development or increase flow through existing collaterals. In addition, when the LV contracts, it faces a reduced aortic pressure to work against, because the counterpulsation has somewhat emptied the aorta. EECP has been primarily investigated as a treatment for chronic stable angina.

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 (MI). In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the development of coronary collateral development. A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually five days per week. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

Regulatory Status

While EECP has been primarily researched as a treatment of chronic stable angina, it has also been used in patients with heart failure. The Vasomedical EECP® Therapy System Model has the following labeled indication under 510(k) clearance from FDA:

“The EECP Therapy System Model TS3 with Pulse Oximetry is a noninvasive external counterpulsation device intended for the use in the treatment of patients with heart failure, stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.”

Cardiomedics Inc. has FDA 510(k) clearance to market the CardiAssist™ Counterpulsation System (K022107) and the CardiAssist ECP System (K010261) for the same indications as the Vasomedical EECP® systems. FDA product code: DRN.

Related Protocol

Transmyocardial Revascularization

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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