

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/14	<b>Next Review Date:</b> 07/21
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 02/07, 11/07, 9/08, 03/09, 01/10, 01/11, 01/12, 01/13, 09/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 07/20	

***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.*

**RELATED PROTOCOL**

Transmyocardial Revascularization

**DESCRIPTION**

Enhanced external counterpulsation (EECP) is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. EECP has been studied primarily as a treatment for patients with refractory angina and 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 afterload, and increase venous return. The proposed mechanism of action is the augmentation of diastolic pressure by displacement of a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and 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. Also, when the left ventricle contracts, it faces reduced aortic counterpressure, 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 acute myocardial infarction. In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the 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 a 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

A variety of EECP devices have been cleared for marketing by the Food and Drug Administration through the 510(k) process. Examples of EECP devices with Food and Drug Administration clearance are outlined in Table 1. Food and Drug Administration product code: DRN

Table 1: FDA-Cleared EECP Devices

Device	Manufacturer	Cleared	Indications
External Counterpulsation System	Vamed Medical Instrument	Sep 2019	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo<sub>2</sub>, and increase blood flow</li> </ul>
Pure Flow External Counter-Pulsation Device	Xtreem Pulse	May 2018	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo<sub>2</sub>, and increase blood flow</li> </ul>
Renew® NCP-5 External Counterpulsation System	Renew Group	Dec 2015	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo<sub>2</sub>, and increase blood flow</li> </ul>
ECP Health System Model	ECP Health	Aug 2005	<ul style="list-style-type: none"> <li>Stable or unstable angina pectoris</li> <li>Acute myocardial infarction</li> <li>Cardiogenic shock</li> <li>Congestive heart failure</li> </ul>
CardiAssist™ Counter Pulsation System	Cardiomedics	Mar 2005	<ul style="list-style-type: none"> <li>Ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction, and cardiogenic shock</li> </ul>
ACS Model NCP-2	Applied Cardiac	Aug 2004	<ul style="list-style-type: none"> <li>Stable or unstable angina pectoris</li> </ul>

Device	Manufacturer	Cleared	Indications
External Counterpulsation Device	Systems		<ul style="list-style-type: none"> <li>• Acute myocardial infarction</li> <li>• Cardiogenic shock</li> <li>• Congestive heart failure</li> </ul>
EECP® Therapy System	Vasomedical	Mar 2004	<ul style="list-style-type: none"> <li>• Stable or unstable angina pectoris</li> <li>• Acute myocardial infarction</li> <li>• Cardiogenic shock</li> <li>• Congestive heart failure</li> </ul>

EECP: enhanced external counterpulsation; FDA: Food and Drug Administration; VO<sub>2</sub>: oxygen consumption

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